AN OPEN CLINICAL STUDY ON "*BALA KARAPPAN*" (ATOPIC DERMATITIS) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG *SAARANAI ENNAI*

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INTRODUCTION

Siddha system is an ancient system of medicine and was found by siddhars who have attained siddhi [spiritual perfection]. Siddhars who really discovered the good of humanity are seers, thinkers and men of action. Siddha system plays a wide ranged role in the field of pediatrics. It ensures the health of the children with its astonishing herbal formulation. Children's health reflects the nation's health and wealth and they are most vulnerable group in the society. They become ill easier since they aren't built with a good immune system and they are exposed to several pathogens from the surrounding environment.

Siddha system of medicine is based upon the 96 *Thaththuvangal.* Among that, *pancha boothas* [five elements are earth, water, space, fire, air] and the three *Uyir Thathukkal* [Three humours- Vadha, Pitha, and Kapham] got prime importance. The disturbance in the equilibrium of the three humors cause the disease. It's explained by thiruvalluvar in his kural,

"மிகினும் குறையினும் நோய்செய்யும் நூலோர்
வளிமுதலா வெண்ணிய மூன்று".

It serving the mankind to all of its physical and mental, social and spiritual components of human beings. The advantage and unique feature is the removal of root cause of the disease and perfect for body and mind.

Skin is the largest organ in human body.Skin and its derivatives and appendages form the integumentary system. Skin derivatives includes nails, hair and several types of sweat and sebaceous glands. The skin forms protective covering of the body skin develops in the third week of the fetal life. The skin at birth is covered by vernix caseosa. The whitish greasy coats have bactericidal properties.

There are so many skin diseases like vitiligo, Lichen planus, Psoriasis, Scabies, Pityriasis alba affecting the children. Most common childhood skin disease is eczema.

In our classical siddha literature there are 18 types of Eczema (karappan) have been described, Signs and symptoms of eczema is nearly co releated to "**BALA KARAPPAN"** mentioned in siddha system of medicine (Balavagadam). According to the siddha text it is characterized by skin rashes, papules, vesicles, pustules, fissures, oozing, ulceration, swelling, itching, hyperpigmentation lesion. The trial drug **"SAARANAI ENNAI" (internal and external medicine)** indicated for Bala Karappan is comparatively safer than synthetic drugs, this poly herbal preparation may be effective to manage Bala Karappan.

AIM AND OBJECTIVES

AIM:

To evaluate the efficacy and safety of the siddha medicine "*Saaranai ennai*" in the treatment of "*Bala Karappan*" (Atopic Dermatitis) in children.

OBJECTIVES:

Primary objective:

- To study the efficacy of *Saaranai ennai* in the treatment of *Bala Karappan* (Atopic Dermatitis)
- To study the safety of the trial medicine *Saaranai ennai.*

Secondary objective:

- To have a detailed analysis of the safety of the drug through
    - Toxicity studies
    - Pharmacological studies
    - Physico chemical analysis.
    - Phyto chemical analysis
- To collect and review the ideas of *Bala Karappan* mentioned in various siddha literature in the aspects of Definition, aetiology and Clinical features.
- To make a correlative study of the Siddha aspect and Modern aspect of my study *Bala Karappan.*
- To record the incidence of the disease with regard to age, sex, socio-economic status, history of food habits and drug ingestion.
- To have an extensive study that how the disease alters the normal conditions which are dealt under *Mukkutra Verupadugal, Envagaithaervu, Udalthaathukkal, Paruvakaalangal, Neerkuri, Neikuri.*
- To determine the effect of trial drug by AEC & ESR
- To determine the clinical symptoms reduction in EASI (Eczema Area Severity Index) Score.
- To use the possible modern parameters in the investigation of the disease, that enhances to observe the progress of the patient.
- To have a clinical trial, to find out the efficacy of the trial medicine "*Saaranai ennai*" (Internal & External medicine) in the treatment of *Bala Karappan (*Atopic Dermatitis*)* in children.

REVIEW OF LITERATURES

SIDDHA ASPECTS

Bala Karappan is one of the eighteen types of Karappan which affects the children. This skin disease was described by various Siddhars in detail about the general etiology signs and symptoms and prognosis.

கரப்பான்

இயல (Definition)

உடலில் திமிர், தினவு, சொறி, புண், தடிப்பு, வெடிப்பு, நீர் கசிதல் ஆகிய குறி குணங்கள் உண்டாக்கி உடம்பின் இயற்கை நிறத்தை வேறுபடுத்தும் நோய் கரப்பான் எனப்படும்.

நோய் வரும் பருவம்

தால பருவம் முதல் வருகை பருவம் வரையுள்ள நான்கு பருவங்களிலும் கரப்பான் நோய் குழந்தைகளுக்கு உண்டாகக்கூடும்.

நோய் வரும் வழி (Etiology)

In Text book Balavagadam, it desccibed the etiology of Karappan as,

"பெருகுஞ் சோள மிறுகும் பெருங்கம்பு
வரகு காருடன் வாழையின் காயொடு
உரைகொள் பாகற் கெளிற்று மீன் உண்டிடில்
விரிவதாய்க் கரப்பானு மிகுந்ததே".

In take of Fish, Mutton, rhizomes, Tubers of some plants and grains like, Kambu (Pennisetum typhoideum), Solam (Sorghum vulgarel, Varagu (Paspalum Scrobicculatum), Karrasi (Oryza Sativa), Vazhaikkai (Muza Paradisiac), Paakal (Momordica Charantica), Kelirrumean (Osteogeniosus militaris) taken by the mother (By breast feed) or child produces Karappan.

According to siddha literature yugi vaidhya chinthamani:

According to Siddha text book Yugi Vaidhya Chinthamani etiology of Karappan described by eating meat, various types of millet and tubers can cause Karappan.

"ஏழான கரப்பானின் உற்பத்திக் கேளாய்
ஏற்றமாய் மாமிசங்கள் புசிக்கையாலும்
கூழான கம்பு தினை வரகு சாமைக்
கொடிதான கிழங்கு வகையருந்த லாலும".

- யூகி வைத்திய சிந்தாமணி

According to siddha literature Pararasa Segaram:

According to the Siddha literature Pararasa Segaram etiology of Karappan described as Air born infection, Excessive intake of Jaggery, Plantain, Brinjal, poisonous bites may cause the disease.

"வேகக் காற்றதினர் பனை வெல்லத்தால்
பாகமிக்கலான மேதிப் பாவெயிலால்
தாகமானி வருக்க திசார்தலால்
மோக வாழை வழுதலை முள்ளிக்காய்
காயும் பல்விடத் தாற்சுரத் தாற்களில்
எயும் வண்டெலி யால் வருமே துவெளி
குடி நல்லறிவான எருவினார்
யானமான கரப்பன் வகைகளே".

- பரராச சேகரம்.

Classification of karappan:

As per the Siddha literature Bala vagadam, Karappan is classified into eighteen types as follows,

"முத்தோட மரியூது சூலை
முன்னுவெடி மண்டை பொரிசட்டை
சற்றேடு கருமையொடு செம்மை.
தனிக்கொள்ளி தோடமொடு வாலை
முற்றோல்வ ரட்சியொடு வீங்கல்
மூரிவரும் பதினெட்டு வகையாம்
கொத்தான கரப்பான்க ளென்று
கூறினார் பண்டையோ ராமால்"

"செங்கரப்பான் அனல்கரப்பன் தானும் மண்டைச்
சிரங்கிபபண்ணும் அரிகரப்பான் பொரிக ரப்பான்
அங்கமதி லெழுகரப்பன் தானு மிக்க
அளராம் உதி ரக்கரப்பன் கட்டி யோடு
பொங்கமாய் வீங்கி கரப்பான னுந்தான்
புகலரிய சட்டைதடி வெடிக ரப்பான்
சிங்கமுக எரிகரப்பன் வாத பித்தச்
சேத்துமத்தோ டேகரப்பன் பதினெட் டமெ
எண்வகைக் கரப்பன் இசைந்திடக் கேளு".

Classification of karappan as per the text book of bala vagadam

1. Vatha Karappan (வாத கரப்பான்)
2. Pitha Karappan (பித்த கரப்பான்)
3. Sethuma Karappan (சேத்தும கரப்பான்)
4. Ari Karappan (அரி கரப்பான்)
5. Oothu Karappan (ஊது கரப்பான்)
6. Soolai Karappan (சூலை கரப்பான்)
7. Vedi Karappan (வெடி கரப்பான்)
8. Mandai Karappan (மண்டை கரப்பான்)
9. Pori Karappan (பொரி கரப்பான்)
10. Sattai Karappan (சட்டை கரப்பான்)
11. Oodu Karappan (ஓடு கரப்பான்)
12. Karung Karappan (கரங்கரப்பான்)
13. Seng Karappan (செங்கரப்பான்)
14. Kolli Karappan (கொள்ளி கரப்பான்)
15. Thoda Karappan (தோட கரப்பான்)
16. Vaalai Karappan (பால கரப்பான்)
17. Varal Karappan (வரள் கரப்பான்)
18. Veengu Karappan (வீங்கு கரப்பான்)

1. வாத கரப்பான்:

"தெறிக்கும் வீங்குமுட லெங்கு மேதிமிர்க டுப்ப தகியழுந் தேகமேற்
பொறிப் பறந்ததென வேபுண் ணாகிய தி லேவெடித் ததிக பொங்கமாய்
முறுக்கி யேசுர மாகி நாவது வறண்டு நோயது முதிர்ந்திடில்
வெறிக் கருங்குழலி மாது வாதகரப் பானெனப் புகல்வர் மேவிடே".

- (பால வாகடம் 4ம் பதிப்பு பக்க எண் 385)

- Skin rashes or bumpy rashes
- Papules/ Vesicles/Pustules
- Oozing fromlesion
- Lymphadenopathy
- Itching
- Fever

2. **அழற்கரப்பான்:**

"கொடுமையான சிரநோயினோடு சொறி கூறு முட்டினமும் வாந்தியும்
கடுமையான சுரமெய்சி வந்திடுதல் கண்பரத் துதொனி முந்தியே
தடைகளாகமல பந்தமாகிவிடில் சார்ந்த பித்தகரப் பானென்றே
விடமு நேரமுத முஞ்சமானவிழி வெண்ண கைத்திரு மருந்திடே".

- Headache
- Itching
- Vomiting
- Fever
- Reddishness in affected skin
- Constipation

3. **ஐயக்கரப்பான்:**

"இசையு நெஞ்சுக ளடைத்து ளேவிரண மாகியேதவை வலித்திடும்
அசையும் வாயதனில் வெந்துமே திரட்சியகி யேகடு கடுத்திடில்
விசையுஞ் சேத்தும கரப்பானென சிகிச்சைமேவு செவ்வரி பரந்து நின்
வசை பொருந்தும் விழி கலைதிரண்டமுக வனிதையே வுடதங்களே".

- Ulcers in the mouth and trunk
- It changes to vesicles
- Chest pain
- Headache

4. **அரிகரப்பான்:**

"இடைசி றுத்துவன கனிபு ரைத்த மொழி யினியதானவத ரத்தினாய்
துடையி டைக்குள்மிகு விரண மாகியதிற் சூழச லங்ககளுமி குந்துநோய்
புடையு நீள்தசை கரைந்து நட்படவி ருந்து பூதவுடல் வாடினால்
அடைவ சோரி கரப்ப னாமிதைய றிந்து நன்மருந் தாற்றிடே".

- Ulcers in the genital organs and both groins
- Itching and oozing in the inner aspect of the thigh
- Emaciation

5. ஊது கரப்பான்:

"கேளாய் குளிர்காய்ச்சல் கேடாங் கருங்கழலை
மூளாவி தான் போல் முயன்றுநிற்கும் - நாள்தோறும்
பூதம்போல் வீங்குவிக்கும் புண்ணாகி மூக்கரிக்கும்
ஊதுகரப் பாந்தோடம் உற்று".

- Fever with rigor
- Tumours in the body
- Generalised oedema and Itching

6. சூலைக் கரப்பான்:

"பிள்ளை முகம்வாடிப் பேதவெடி மேனியெல்லாம்
சள்ளை பொருந்தித் தவிக்குமே – மெள்ளக்கேள்
வள்ளல் முழங் கால்கை மருவியுண்ணக் கூடாது
தள்ளுமென்றே சூலையது தான்."

- Ulcers and pain in the body and general debility
- Difficulty in moving both knees and elbow joints

7. வெடி கரப்பான்

"அரிவை யேயுடலகளெங்கும் விங்குமசைகீலில் வீங்குமதில் துண்டமாய்
விரிய வீங்கியதி லெவெடித்திடு மிகுந்த வெப்பதுவு மாகவே
திரிகி யேதலை வலித்து மேலும்வெகு தினவு மாகியது வோடினால்
உரிய தாகும்வெடி கரப்ப னாமென வுகந்து பண்டித முணர்த்திடே".

- Swelling in the body
- Pain and swelling all over the joints
- Itching, headache, and fever

8. மண்டைக் கரப்பான்:

"ஓடி மண்டைதனி லேபுண் ணாகியுயர் காதிற் சீவழிந்தறியே
நாடி யேதலைவ லித்து மூக்கினில் நயந்து நிரது ப்ரிந்திடும்
வாடி மெய்யதும் வெப்பமொடு குரல் வளையி னினறினவுமாகவே
கூடில் மண்டைக் கரப்பானெ னப்பரி கார மேலினிக் கூறுவாம்".

- Itching in the scalp
- Ear discharge, headache, and fever
- Loss of weight and pain in the throat

9. **பொரிகரப்பான்**:

"மாறு மாறென வடிதத வயென வுடற்குளே தடிப்பாகியே
ஏறு மேசிவந் தோடு யேகனத் தெங்கு மேல்வெடித் துள்ளுமே
நீறு போலனல் குளிர்ச்சி யாகியுழ னாவு லர்ந்துநெறி தாழ்த்திடில்
ஆறி டாப்பொறி கரப்ப னாமென வறிந்து பண்டிதந் தொகுத்திடே".

- Papules in the body and altered sensorium
- Dryness of mouth

10. சட்டைக் கரப்பான்:

"மங்கை கீலில்வலி கள்ளிப் பூவெனம லர்ந்து வாரியிடு மெய்யினிற்
போங்கு நீர்ப் பனிகள் போல்வி முந்துடலம் வெப்ப மாகிமலஞ் சிக்கியே
துங்க மானசிர நோவு மாகிவளர் தூயவன்னமது துவேடமாம்
தங்கு சட்டை கரப் பானே ணச்சிகிச்சை தானே தற்குவிரித் தோதுவாய்".

- Pain in all the joints associated with fever
- Yellow colouration of the skin
- Itching and oozing in the lesion
- Loss of appetite

11. ஓடு கரப்பான்:

"எண்ணு கின்றதொரு கீலி லேவலிக ளேக மாகியது கட்டியே
வண்ண மெய்நரம் பெங்கு மேயிசிவு குத்த லாகிமல பந்தமாய்
நண்ணி யேதினவு மாய்த்தடித் துடலி னடி வீக்கமு மிகுந்திடிற்
கண்ணி ஓடுகரப் பான்இ தென்றமுறை கண்டு கொள்ளடி கருத்திலே".

- Pain and swelling in all the joints
- Difficult to flexion and extension of joints
- Allergic papules
- Itching
- Constipation

12. கருங்கரப்பான்:

"அற்ய கேளய் கரங்கரப்பன் அழமெ குழவி உடல்வெதும்பும்
செறிய முலையும் உண்ணாது தேகநிற்கும் வெவ்வேறாய்க்
கரிய மேனி பசுநரம்பு கதித்தே காட்டும் பரபரத்து
முறுக்கி மிகவுந் துள்ளி விழும் முகமும் பதங்கள் ஊதிடுமே".

- Fever
- Discolouration of the skin
- Oedema in the face and lower limbs

13. செங்கரப்பான்:

"காய்ச்ச லோடுகடுப் பகி யூதிடல் கன்றி மெத்தவு மழன்றுபோய்
மேய்ச்ச லானதின வாகியெங்கணு வியர்க்குருவுகள் மிகுந்துதான்
பாய்ச்ச லானமுக முங்கறுத்துடல் பரிந்து தானது சிவந்திடில்
சூட்ச மாகிவளர் செங்க ரப்பனெனத் தோற்றி யேயவு டதஞ்செயே".

- Low grade Fever
- Macules and papules are present
- Blackish discolouration in the face
- Erythematous lesion present in all over the body

14. கொள்ளிக் கரப்பான்:

"கொத்துக் கொள்ளி யின்கரப்பான் குணத்தைக் கேளாய் கோகிலமே
மற்றும் வயிறு தான்வீங்கி மலமு மடைக்கும் இளைப்புண்டாம்
கத்துங் குரலும் அரையுண்டாங் கனத்த விக்கல் உண்டானால்
பத்தும் பதியும் ஒதுவதேன் பாலன் பிழைப்ப தரிதாமே".

- Abdomen swelling
- Constipation
- Emaciation
- Hiccough
- Dyspnoea

15. தோடக் கரப்பான்:

"உள்ளு மேலுநளிர் காய்ச்ச லாகியுடம் பெங்கும் புண்ணென வழன்றுவாய்
கள்ளு நாறியுடல் தன்னி லேகழலை கண்டு பூதமென வீங்கியே
எள்ளின் மாமலரை யொக்கு மூக்கின் நின்றழுது மேங்கினால்
தள்ளு மான்களின் சாய லாய் கொடியதோ டமானகரப் பானிதே".

- Fever with rigor
- Papules and pustules in the body
- Foul smell in mouth
- Lymphnode enlargement
- Itching innose

16. வாலை(பால) கரப்பான்:

"காலது கடுக்குஞ் சந்து கண்டமும் வெடித்துப் புண்ணாய்
ஏலவே கடிவி டம்போல் இருத்துபன் னீர்பேல் பாய்ந்து
கோலமாய் வற்றி நாறும் குழவியு மொடுங்கு மாகில்
மாலருங் குழலாய் வால கரப்பான் செய் வாறு தானே".

- Pain in the lower extremities
- Appearance of vesicles, oozing, bullae, papules
- Foul smelling discharge in the ulcers

17. வரள் கரப்பான்:

"உச்சிமுத லுள்ளங்கா லுற்றளவி லெவ்விடமும்
நச்சுச் சிறுசிரங்கு நண்ணியே-நிச்சல்
வெடித்து நீர் மெவு நமை மெவா துறக்கம்
கடிந்தவரட் சிக்கரப்பான் காண".

- Itching, Oozing, papules in the body
- Bullae present in the whole body
- Insomnia

18. **வீங்கு கரப்பான்:**

"முன்னரே யங்கங்கு மூரிக் கனமுண்டாய்ப்
பின்னரவை புண்ணாய்ப் பெருஂதீயாய்ப-மன்னியெரிந்
தப்பான முத்தணிந்தவற்றி னீர் சொரிதல்
தப்பாவிங் குங்கரப்பான் தான்".

- Swelling in various parts of the body
- Burning sensation in the site of the lesion
- Oozing

Other Siddha Literatures describing the classification of Karappan

As per the another siddha text book "*Aathma rakshamirtham yennum vaithiya saarasankiram"* describes the classification of Karappan in eighteen types as follows,

a) ஆத்மா ரத்சாமிர்த்மென்னும் வைத்திய சாரசங்கிரம்

1. வாதக் கரப்பான்
2. பித்த கரப்பான்
3. சிலேத்தும கரப்பான்
4. செங்கரப்பான்
5. கருங்கரப்பான்
6. மண்டை கரப்பான்
7. அரி கரப்பான்
8. பொரி கரப்பான்
9. கிரந்திக் கரப்பான்
10. சூலைக் கரப்பான்
11. வாலைக் கரப்பான்
12. ஊது கரப்பான்
13. செவ்வாப்பு கரப்பான்
14. கொள்ளி கரப்பான்
15. கட்டியொடுவிங்கு கரப்பான்
16. உதிரக் கரப்பான்
17. சட்டைதடிவெடி கரப்பான்
18. சிங்கமுக எரி கரப்பான

b) யூகி வைத்திய காவியம்

As per the siddha literature *Yugi vaithiya kaaviyam karappan* is classified into 9 types as follows,

1. வாதக்கரப்பான்
2. கண்டக்கரப்பான்
3. வறட்சிகரப்பான்
4. பித்தகரப்பான்
5. பித்தவறட்சிக்கரப்பான்
6. கபால கரப்பான்
7. வாதவறட்சிக்கரப்பான்
8. திமிர்வாதக்கரப்பான்
9. செங்கரப்பான்

c) சிகிச்சாரத்ன தீப வைத்திய சிந்தாமணி

As per the siddha literature *Sigicha rathna theepam*, karappan is classified into 7 types as follows,

1. வாதக் கரப்பான்
2. திமிர் கரப்பான்
3. கபால கரப்பான்
4. கண்டக் கரப்பான்
5. பித்த கரப்பான்
6. வறட்சி கரப்பான்
7. சிலேத்தும் கரப்பான்

d) குருநாடி சாஸ்திரம்

Other Siddha Literature *Guru naadi saasthiram*, Karappan is classified into eighty five as follows,

"படுவன் முப்பத்திரண்டு பருவெரு நாற்பத்தொன்று
முருகிடும் விஷபமாறு முற்றுமொஷசி மூன்றுர்
திருகிடும் பீலி மூன்று சிரசினிற் சிலந்தி சொல்லில்
கடுகிடு மைடம் பத்தாறு கரப்பானு மென்பத்தைந்து".

- (குருநாடி சாஸ்திரம்)

e) அகத்தியர் 2000

In *Agathiyar 2000* classification of Karappan is sixty six in numbers

"விளம்பிடு வாதநொவு எண்பத்து நாலுமிக்க
உள்ளங்கள் சன்னி முப்பதோங்குடல் வாயுமெட்டு
கழங்கமு முப்பத்தெழு கரப்பானு மறுப்பத்தாறு
தனங்கொள்ளிப் புருதி நாலு சாற்றுளை குறவை யெட்டே".

- (அகத்தியர் 2000)

f) அகத்தியர் இரண நூல்

In *agathiyar irana nool* classification of Karappan is sixty six in numbers

"எண்பது கரப்பான் தன்மை யியம்பிடுமாறு கேளீர்
நன்யிடும் வாதம் பித்தம் நலங்கெட்டுத் தாளம்விங்கும்
புண்படுங் கரங்கள் சந்து புலைந்திடல் கருத்து நோகும்
வன்மையுடன் வெடித்துச் சூலை வருவதுரபை தென்வெ".

- (அகத்தியர் இரண நூல்)

g) யூகி வைத்திய சிந்தாமணி

As per the Siddha literature *Yogi Vaithiya Chinthamani* Karappan is classified into seven types

"ஆமென்ற கரப்பான் தான் ஏழுவித மாகும்
அடங்காத வாதத்தின் கரப்பானோடு
காமென்ற கண்டமாங் கரப்பானாகும்
கருதிய தோர் வறட்சியாங் கரப்பானோடு
தேமென்ற திமிர்வாதக் கரப்பான் றானும்
சிரசினிலே பெருக பாலக் கரப்பான்
போமென்ற பித்தமாங் கரப்பானோடு
பெரிய சேட்டுமக் கரப்பான் பெயர்தானேழே".

- (யூகி வைத்திய சிந்தாமணி)

1. Vadha Karappan (வாத கரப்பான்)
2. Pitha Karappan (பித்த கரப்பான்)
3. Kabha Karappan (கப கரப்பான்)
4. Kanda Karappan (கண்ட கரப்பான்)
5. Varatchi Karappan (வறட்சி கரப்பான்)
6. Kabala Karappan (கபால கரப்பான்)
7. Thimir Vatha Karappan (திமிர்வாத கரப்பான்)

Curable and incurable types of karappn as per siddha text book baavagadam

1. கொள்ளி கரப்பான் - அசாத்தியம் (Incurable)
2. மற்ற 17 வகைகள் - சாத்தியம்(Curable)

முக்குற்ற வேறுபாடுகள் (Pathogenesis)

சித்த மருத்துவத்தில் முக்குற்றங்களின் அடிப்படையில் நோய்கள் வகைப்படுத்தப்பட்டுள்ளன. முக்குற்றறங்களாவது வாத, பித்த, கபம் என்று கூறப்பட்டுள்ளது அவை முறையே

வாதம் -10
பித்தம் -5
கபம் -5

வாதம் / வளி (Vatham)

வடிவத்தன்மை

- நுண்மை (அணுத்துவம்)
- நொய்மை (கடினமின்மை)
- தன்மை (குளிர்ச்சி)
- வெம்மை (உட்டிணம்)

தன்மை, வெம்மை ஆகிய இவ்விரண்டால் வரும் ஒப்புரவின்மை (சருச்சரை) என்பனவாம்.

வளி வாழுமிடம் (Location of Vatham in the body)

அபானம், மலம், இடகலை, உந்தியின் கீழ் மூலம், காமக்கொடி, இடுப்பு எலும்பு,
தோல், நரம்புக்கூட்டம், கீல்கல், மயிர்க்கால்கள், ஊன் ஆகிய இடங்களில் வாழ்வதாகும்.

வகைகள்	பணிகள்
1. பிராணன்	• மூச்சு வாங்கல், விடுதல் செய்யும். • புசிக்கும் உணவுகளைச் செரிக்கப் பண்ணும்
2. அபானன் (கீழ்நோக்குகால்)	• மலசத்தைத் தள்ளும் • ஆசனவாயைச் சுருக்கும் • அன்னசாரத்தைச் சேர வேண்டிய இடங்களில் சேர்ப்பிக்கும
3. வியானன்	• உறுப்புகளை நீட்ட மடக்கச் செய்தல் • பரிசங்களையறிதல் • உண்ணும் உணவின் சாரத்தை அவ்வவ்விடங்களில் நிரப்பித்து உடலைக் காக்கும
4. உதானன் (மேல் நோக்குக்கால்)	• உணவின் சாரத்தை அங்கங்கே நிறுத்தும். வெளிப்படுத்தியும்/ கலக்கியும் வருதல் செய்யும்
5. சமானன் (நடுக்கால்)	• வாயுக்களை மிஞ்சவொட்டாமல் மடக்கிச் சரிபடுத்தி சேரபண்ணும். • தண்ணீர், அன்னம் ஆகியவற்றை சமப்படுத்தி உடலிலெல்லாம் சேரும்படி செய்யும்

6. நாகன்	• அறிவை எழுப்பல். நல்ல பண்களைப் பாடுவிக்கும். • கண்களை திறக்க இமைக்கச் செய்யும் • மயிர்களை சிலிர்க்கப் பண்ணும
7. கூர்மன்	• இசையை கொட்டுவித்தல் • கொட்டாவி விடப்பண்ணல் பலம் உண்டு பண்ணல் • கண்களை திற்க்க/மூட பண்ணல். • உலகப் பொருட்கள் யாவற்றையும் கண்களுக்கு காண்பிக்கும். • கண்களினின்று நீரை விழப் பண்ணும
8. கிருகரன்	• நாவிற்கசிவு, நாசியிற் கசிவையும் உண்டாக்கல். • பசியை உண்டு பண்ணல் • ஒன்றை நினைத்திருக்கச் செய்தல் • போதற் தொழிலைச் செய்யும் • தும்மயலயம், இருமலையும் உண்டாக்கல்
9. தேவதத்தன	• சண்டைகொள்ளல் • தர்க்கம்பேசல், மிக்க கோபம்.
10. தனஞ்செயன்	• மூக்கிலிருந்த தடிதது உடம்பு முழுமையும் வீங்கப் பண்ணும். • காதில் கடல் போலிரையும். • காற்றெல்லாம் வெளிப்பட்ட பின்னர் 3வது நாளில் தலை வெடித்த பின் தான் போகும்

பாலக் கரப்பானில் அபானன், உதானன், சமானன், கிருகரன், தேவதத்தன் இவைகள் பொதுவாக பாதிப்பு அடையும்.

பித்தம்/அழல் (Pitham)

வடிவத்தன்மை

- வெப்பம்
- நெய்ப்பு
- கூர்மை
- நெகிழ்ச்சி

பித்தத்தின் இருப்பிடன்:

பிங்கலை, பிராணவாயு, நீர்ப்பை, மூலாக்கின், இருதயம், தலை ஆகிய இடங்களில் வாழ்வதாகும்.

வகைகள்	பணிகள்
1. அனர்பித்தம்	• உண்ட உணவை செரிக்கும்படி செய்யும்
2. இரஞ்சகம்	• செந்நீரை மிகுதிபடுத்தும். • உணவின் சாற்றுக்கு செந்நிறத்தைக் கொடுக்கும்
3. சாதகப்பித்தம்	• நிறைவேற்றும் பண்புடையது • மனம், புத்தி, பற்று இவற்றைக் கொண்டு விருப்பமான தொழிலைச் செய்து முடிக்கும
4. ஆலோசகப்பித்தம்	• கண்களுக்கு பொருட்களைத் தெரிவிக்கும் பண்புடையது.
5. பிராசக பித்தம்	• தோலுக்கு ஒளியைக் கொடுத்து ஒளிரச் செய்யும்

பாலக் கரப்பனில் இரஞ்சகம், பிராசகம் இவைகள் பொதுவாக பாதிப்பு அடையும்.

ஐயம்/கபம் (Kabham)

வடிவத்தன்மை

- தன்மை
- மந்தம்
- நெய்ப்பு
- திண்மை
- வழுவழுப்பு
- மென்மை

ஐயம் வாழுமிடம்

சமானவாயு, சுழிமுனை, வெண்ணீர (விந்து), தலை, நாக்கு, உண்ணாக்கு, கொழுப்பு, மச்சை, குருதி, மூக்கு, மார்பு, நரம்பு, எலும்பு, பெருங்குடல், கண், கீல்கள் ஆகிய இடங்களில் வாழ்வதாகும்.

வகைகள்	பணிகள்
1. அவலம்பகம்	• மற்ற நான்கு ஐயங்கட்கு பற்றுக் கோடாயிருத்தில்
2. கிலேதம்	• உணவுப் பொருள், நீர் இவைகளை ஈரப்படுத்தி மெத்தெனச் செய்யும் தொழிலைப் புரியும்.
3. போதகம்	• நாவினின்று உண்ணுகிற சுவைகளை அறிவிக்கும் தொழிலைப் புரியும
4. தற்பகம்	• தலையினின்று கண்களுக்கு குளிர்ச்சியைத் தரும்.
5. சந்திகம்	• பூட்டுகளில் நின்று இயற்கையாய் எல்லா கீல்களையும் ஒன்றொடொன்று பொருத்தி தளரச் செய்து கொண்டிருக்கும்.

பாலக் கரப்பானில் ஐயம் பொதுவாக பாதிப்பு அடையாது.

Diagnostic Methods (Piniyarimuraimai)

Piniyari Muraimai is the methods of determination of a disease. It is bassed on the following principles.

1. Poriyalarithal (Inspection)
2. Pulanal arithal (Palpation)
3. Vinaathal (Interrogation)

Poriyalarithal and pulanal arithal goes hand with the concept of Examining the patient's pori and pulan with that of physician's pori and pulan.

Vinaathal is a method of interrogation about the details of that patients problem from his own words (or) from his parents or neighbours who are taking care of the patients, when the patient is not able to speak (or) patient may be child.

சித்த மருத்துவத்தின் நோய்கணிப்பில் பின்வரும் காரணிகள் முக்கிய பங்கு வகிக்கின்றன.

நோயாளியைச் சார்ந்தது:

1. உயிர் தாதுக்கள் (முக்குற்றம்)
2. உடல் தாதுக்கள் (ஏழு உடற்கட்டுகள்)
3. எண்வகைத் தேர்வு

4. பொழுது

1. சிறுபொழுது - வைகறை, விடியல், எற்பாடு, நண்பகல், மாலை, யாமம்
2. பெரும்பொழுது- கார், கூதிர், முன்பனி, பின்பனி, இளவேனில், முதுவேனில

5. ஐவகை நிலங்கள் - குறிஞ்சி, முல்லை, மருதம், நெய்தல், பாலை.

மேற்கூறிய காரணிகளின் மாறுபாடுகளை ஒன்றுடன் ஒன்று ஒப்பிட்டு நோய் கணிக்கப்படுகிறது.

Ennvagai thervugal (eight fold examination)

Envagai thervugal is a tool and it is described by Siddhar theraiyar as follows

"நாடிப் பரிசம் நா நிறம் மொழிவிழி
மலம் மூத்திர மிவைமருத்துவ ராயுதம்".

- தேரன்

The above concept also supported by another great Siddhar Agasthiyar in Vaidhya Chinthamani Venba – 4000 as follows,

"மெய்குறி நிறம் தொனி விழி நா இருமலம் கைக்குறி"

Another Siddha book describe Envagal thervugal as follows,

"தேடிய வியாதிக் கெல்லம் தேகத்தில் பரிட்சையுண்டு
கூடியே நிற்குமெட்டு பரிட்சையாங் கூறக்கேளீர்
நாடியே தொட்டாற் தேகம் மூத்திரம் வார்த்தை கண்கள் நாக்கு
பாடியே மலசலங்கள் பல வண்ணம் பார்த்துக் கொள்ளே"

- சித்த மருத்துவமணிகள்

மேற்கூறிய பாடலின் மூலம் நாடி, ஸ்பரிசம், நா, நிறம், மொழி,விழி, மலம், மூத்திரம் ஆகியன மருத்துவரின் ஆயுதம் போன்றவை என அறியலாம்.

Hence the diagnosis is made by using the following tools are important in Siddha system of Medicine:

1. Naadi (Pulse reading)
2. Sparisam (Tacfile sensation)
3. Naa (Tongue)
4. Niram (Colour)
5. Mozhi (Speech (or) Voice)

6. Vizhi (Eye)
7. Malam (Stools)
8. Moothiram (Urine)

1. Naadi

"உடலில் உயிர் தரித்திருப்பதற்கு காரணமான சக்தி எதுவோ அதுவே நாடி"

Naadi is the vitiating elements of the body such as Vatham, Pitham, Kabam. Naadi is otherwise called a Uyir thathukkal.

Naadi can be felt by a Physician viz Vatham, Pitham and Kabam with the tips of Index, Middle and Ring fingers respectively at the anterior part of lower end of the radius bone of the patients. It informs the physiological and pathological condition of the body.

The three Uyirthathukkal are formed by the combination of

Edakalai + Abanam = Vatham

Pinkalai + Piranan = Pitham

Suzhumunai + Samanan = Kabam

The ratio between Vatham, Pitham and Kabam is 1:1/2:1/4 respectively.

In Bala Karappan, Vatha naadi generally affected and then other naadi's are also deranged.

2. Sparisam

The following points are elicited through sparisam. Temparature of the skin, Hypersensitiveness and thickness of the skin, swelling and dryness of the skin, ulcers, oedema, obesity, liver and spleen enlargement.

In Bala Karappan, the skin becomes well defined borders, with clear central hyperpigmentation

3. Naa

This is the method of inspection of the tongue, gums, teeth, lips, palate etc.,

4. Niram

Changes in the colour of the skin, teeth, eyes, nail and lips due to Mukkutra derangement are to be noticed Hypo (or) hyperpigmentation is also be noted.

In Bala Karappan skin is hyperpigmented, erythemators, macular, slightly raised margenated with central clearing in nature.

5. Mozhi

Examination of Mozhi includes clarity of speech, crying, low and high piched voice, slurring speech.

No abnormalities were observed in Bala Karappan.

6. Vizhi

Pallor of the conjunctiva, conjunctivitis, cataract (any redness and pterygium etc.)

No abnormality was seen in Bala Karappan.

7. Malam

Semisoild, colour, froth, abnormal consistency, frequency, constipation, foul smell etc,.

In Bala Karappan constipation may be present.

8. Moothiram

Examination of urine for the determination of Neerkuri and Neikuri. It is one of the important diagnostic method.

நீர்க்குறி (Neerkuri)

"வந்த நீர் கரியெடை மணம் நுரை எஞ்சலென்
றைந்தியலுளவை யறைகுது முறையே"

\- நோய் நாடல் முதல் பாகம்

நீரில் நிறம், மணம், நுரை, எடை, எஞ்சல், ஆகியவற்றை நோக்க வேண்டும்.

"ஆடிக்கலசத் தாவியே காது பெய்
தோருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்குறி நிருமித்தல் கடனே"

\- தேரன்

Prior to the day of urine Examination the patient should have good sleep and instructed to take a balanced diet. After waking up in the morning, the first voiding urine is collected in a clear wide mouthed glass container and is subjected to analysis of "Neerkkuri" within 1½ hours.

Urine has the following general features

- Niram
- Edai
- Manam
- Nurai
- Enjal

நெய்க்குறி (Neikkuri):

குழந்தைகளின் நாடிநடை சரியாக கணிப்பதில் சிரமம் உள்ளதால், நெய்க்குறி பரிசோதனை மூலம் நோயாளர் எக்குற்றத்தால் பாதிக்கப்பட்டுள்ளார் என்பதனை கணிக்கலாம்.

பாலக் கரப்பான் நோயாளியின் சிறுநீரை சோதனை வட்டிலில் ஊற்றி ஒளிமிகுந்த இடத்தில் நீரின் அலையில்லாத போது நல்லெண்ணெயத்துளி விட்டு பார்க்கப்பட்டது. சிலரில் அரவென நீண்டும ஆழி போல் (மோதிரம்) பரவியும், சிலரில் முத்து போல் நின்றும் காணப்பட்டது.

"அரவென நீண்டின் அ.ஃ.தே வாதம்
ஆழிபோற் பரவின் அ.ஃ.தே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே".

\- நோய் நாடல் முதல் பாகம

''எண்ணெய் விட்டு பார்க்கும் விதி
நிறக்குறி குரைத்த நிருமாண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்
னின்றதிவலை போம் நெறிவிழியறிவும்
சென்றது புகழுஞ் செய்தியை யுணரே''.

The collected specimen (urine) is kept open in a glass dish or china clay container. It is to be examined under direct sunlight, without any shaking of the vessel. Then add one drop of gingelly oil without disturbing the urinary specimen and the NeiKuri was noted in direct sunlight and conclude the diagnosis as follows,

Character of Vathaneer

"ஆரவென நீண்டின.ஃ.தே வாதமே".

When the oil drop lengthens like a snake, it is called "Vatha Neer"

Character of Pithaneer

“ஆளி போற்பரவின் அ.ஃதே பித்தம்”.

When the oil drop spreads like a ring, it is called “Pitha Neer”

Character of Kabaneer

“முத்தொத்து நிற்கின் மொழிவதென் கபமே”.

When the oil drop appears like a pearl, it is called “Kaba Neer”

Character of Thonthaneer

Snake in the ring, ring in the snake, snake in the pearl and ring in the pearl are the characters of “Thontha Neer”.

Types of land (Nilam)

Nilam is classified into 5 types depending on the surrounding vegetation, landscape and ecological state study of 5 places is very much necessary as some diseases are common in particular land

1. Kurinji- Mountain and its surroundings liver diseases and fluorosis are common.
2. Mullai - Forest and its surroundings pitha noi and liver diseases are common.
3. Marutham- Field and its surroundings. The ideal places for healthy living.
4. Neithal- Sea and seashores. Liver disease occurs in combination with other diseases.
5. Paalai - Desert and its surroundings.Vatha, Pitha, Kabha, diseases occur.

The disease Bala Karappan was predominant in Neithal nilam.

Paruvakalam

Siddhars have classified a year into six seasons each containing two tamizh months.

1.	Kaarkalam	- Avani & Purattasi	(Aug 18 to Oct17)
2.	Koothirkamam	- Ippasi & Karthika	(Oct 18 to Dec 15)
3.	Munpanikalam	- Margazhi & Thai	(Dec 16 to Feb12)
4.	Pinpanikalam	- Masi & Panguni	(Feb 13 to Apr13)
5.	Elavanilkalam	- Sithirai & Vaigasi	(Apr15 to June14)
6.	Muthuvenilkalam	- Aani & Aadi	(June15 to Aug15)

Udal Vanmai (Body Immunity)

The vanmai is classified into three kinds.

They are,

1. IyarkaiVanmai- Natural immunity of the body caused by Mukkutram right from birth onwards.
2. KalaVanmai- Development of immunity according to age and environment.
3. SeyarkaiVanmai- Improving the health by intake of nutritients, food materials, exposure to some disease, activities and medicines.

Udal thathukkal (Seven udal kattugal)

Udal thathukkal	**General definition of each type**
Saram	Gives strength to body and mind
Seneer	Responsible for knowledge, strength, boldness, healthy, complexion.
Oon	Gives structure and shape to body and is responsible for movements of the body
Kozhuppu	Lubricates the internal organs and helps the organs to Work smoothy.
Enbu	Protects the vital organs and act as basis for movements and maintains body structure.
Moolai	Present inside the bones and it gives strength and maintains the normal condition of the bone.
Sukilam/ Suronitham	Responsible for reproductive function

Human body is made up of seven udal kattugal which are important for the structure and function of the body. Among the seven udal kattugal (seven physical constituents) saaram and seneer are commonly affected in bala karappan.

Management of Bala Karappan in Siddha System

"மிகினும் குறையினும் நோய்செய்யும் நூலோர்
வளிமுதலா வெண்ணிய மூன்று".

- திருக்குறள் 941

In Siddha system the main aim of the treatment is to set right the derangement of mukkutram. Treatment is not only for perfect healing but also for prevention and rejuvenation. It is also very much essential to know the disease through its aetiology.

The nature and severity of the illness, the seasons and the time of occurance must be observed clearly.

Line of treatment

Line of treatment is as follows,

a) Kaappu (Prevention)
b) Neekam (Treatment)
c) Niraivu (Restoration/Rejuvenation of wellbeing)

1**. Kaappu (Prevention of BalaKarappan)**

- Use warm water for bath
- Take bath daily and avoid bathing in lake, pond.
- Use green gram powder or "Nalangu Maa" instead of soap for bath.
- Wash in dresses with disinfectant solution and dry in direct sunlight.
- Prevent from Mosquito bite.
- Advised to wear fresh dry and cotton clothes.
- Advised to trim the nails
- It is a good habit to wash hands after touching other people or animals.

General instructions for Eczema patients

- The patient should not scratch and keep his nails short.
- The diet should be light. The exact composition of the diet depends upon the History of the patients, the diet habits and the results of the allergy test.
- Allergic stuffs should be avoided.
- Healthy hobbies and playing should be encouraged and speed up recover

Neekam (Treatment)

The aim of Neekam is based on

- To bring the deranged three humours to equilibrium state.
- To treat the patient with
    - Internal Medicine
    - External Medicine
- Diet restictions

3. Niraivu (Rejuvenation)

Physical, psychological, social and economic rehabilitation and reassurance of individuals is known as Niraivu.

- Rest
- Positive mental attitude
- Life style modification

மருத்துவம்

1. வேற்றுநிலை வளர்ச்சியடைந்த வாதத்தினை தன்னிலைப்படுத்தவேண்டும்
2. தன்னிலை வளர்ச்சியடைந்த ஐயத்தினை சமப்படுத்தவேண்டும்
3. பித்தகுற்றத்தால் பாதிப்படைந்துள்ள வாதத்தினையும் சரிப்படுத்தவேண்டும்.
4. வன்மை இழந்த உடற்கட்டுகளை வன்மை அடையச் செய்யுமவகையில் மருந்தளிக்கவேண்டும்.

Keeping in mind the need for bringing out an effective therapy for Bala Karappan from Siddha system of Medicine, the author has undergone this dissertation work with *Saaranai ennai* (Internal and Enternal Medicine). The dosage of Medicine all 6 – 12 years : 1-2 ml (int), 30ml(ext).

MODERN ASPECT
SKIN ANATOMY

INTRODUCTION

The skin is composed of a superficial epithelial layer- the Epidermis, and an underlying connective tissue layer- the Dermis or Corium. Beneath the corium is another connective tissue layer- the Hypodermis or subcutaneous layer. It makes up 16% of total body weight, with a surface area of $1.8m^2$. The thickness of skin varies from 0.5mm to 4.0mm.

EPIDERMIS

The mature Epidermis is formed of non-vascular stratified epithelial tissue composed of predominantly keratinocytes. The function of epidermis is protection of the organism from the external environment through physical, chemical, and immunologic barrier functions. Its usual thickness is between 0.07mm and 0.12 mm. It is thickest on the palms of the hand and soles of the feet. The epidermis is mainly divisible into two main systems keratinizing or Malpighian system (Keratinocytes) which forms the bulk and the pigmentary system (Melanocytes) which produces the pigment. The epidermis consists of Squamous cells (Keratinocytes), Melanocytes (The pigment forming cells), Langerhans cells(Dentritic cells of the mononuclear phagocyte system).

LAYERS OF EPIDERMIS

- **Stratum germinatum** -This is the deepest portion of the epidermis and is composed of columnar cells placed perpendicular to the skin surface. The whole of the epidermis germinates from this stratum hence the name "stratum germinatum".
- **Stratum malpigii**– It is superficial to the basal cell layer and is composed of several layers of polyhedral cells connected to each other by intercellular bridges.
- **Stratum granulosum**- It is superficial to stratum malpighii. It is composed of flat, fusiform cells which are one of the three layers. These cells contain irregular granules of Keratohyalin and lysosomal enzymes and cystine rich proteins.

- **Stratum lucidum–** It is superficial to the stratum granulosum. It is pale, wavy-looking layer known as stratum lucidum which is formed by many layers of flattened and closely packed cells.
- **Stratum corneum-** This is the most superficial layer, the outer surface of skin which is exposed to the atmosphere. It is formed by many layers of non nucleated, flattened, cornified cells.

DERMIS

The dermis forms a tough, pliable, fibrous supporting structure between the epidermis and the subcutaneous fat. The thickness of the skin is 1-3 mm. It is profusely supplied with blood vessels. The connective tissue cells in the dermis are spindle shaped fibroblast that is responsible for the synthesis of collagen, elastic fibres and mucopolysaccharides. Phagacytic histocytes, mast cells and motile leukocytes are also present. Within the dermis blood vessels, lymphatics, neural structures, eccrine and apocrine sweat glands, hairfollicles, sebaceousglands and smooth muscle are present. Morphologically, the dermis can be divided into two layers, the superficial papillary layer that interdigitates with the reteridges of the epidermis and the deeper reticular layer that lies beneath the papillary dermis. The extracellular matrix of the dermis consists of collagen and elastic fibers embedded in an amorphous ground substance. Collagen provides strength and stability to the dermis, while elastic fibers allow for elasticity.

SUBCUTANEOUS TISSUE

The panniculus, or subcutaneous tissue, consists of fat cells and fibrous septa that divide it into lobules and anchor it to the underlying fascia and periosteum. Blood vessels and nerves are also present in this layer which serves as a storage depot for lipid, an insulator to conserve body heat, and a protective cushion against trauma.

APPENDAGEAL STRUCTURES

HAIR

Hair follicles are distributed throughout the skin, except in the palms, soles, lips and glans penis. Individual follicles extend from the surface of the epidermis to the deep dermis.

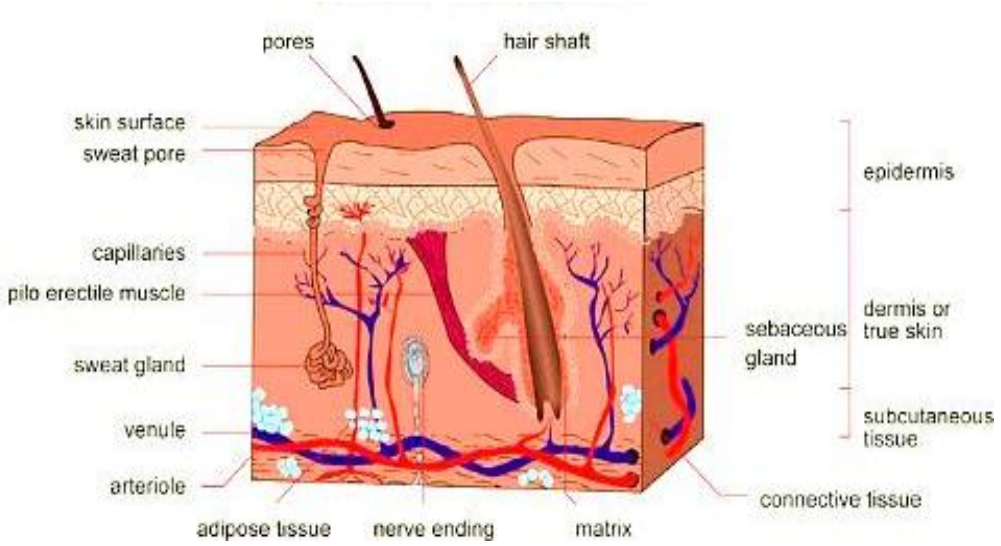
The hair follicle is divided into four segments:

- The infundibulum, which extends from the skin surface to the sebaceous duct.
- The isthumus extending from the sebaceous duct opening to the bulge.
- The lower follicle between the bulge and the hair bulb and
- The hair bulb.

The bulge is the insertion of the arrector pili muscle and is a focus epidermal stem cells. The bulb is where the matrix cells and dermal papilla are involved in formation and maintenance of the hair. Each hair follicle is lined by germinative cells, which produce keratin and melanocytes, which synthesis pigment. The hair shaft consists of an outer cuticle, a cortex of keratinocytes and an inner medulla. The root sheath which surrounds the hair bulb is composed of an outer and inner layer. Hair growth is under endocrine control. Hair grows about 1-2 cm per month.

ANATOMY OF THE SKIN

CROSS SECTION OF THE SKIN



SEBACEOUS GLANDS

Sebaceous glands occur in all areas except the palms, soles and dorsal feet and are most numerous on the face, upper chest and back. They are situated in upper half of the corium. Their ducts open into the hair follicles except on the lips, prepuce and labia minora, where they emerge directly onto the mucosal surface. These holocrine glands are saccular structures that are often branched and lobulated and consist of a

proliferative basal layer of small flat cells peripheral to the central mass of lipidized cells. The latter cells disintegrate as they move toward the duct and form the lipid secretion known as sebum, which consists of triglycerides, wax esters, squalene and cholesterol esters. The purpose of sebum production likely relates to hydrophobic skin carrier function. Sebaceous glands depend on hormonal stimulation and are activated by androgens by puberty. Fetal sebaceous glands are stimulated by maternal androgens and their lipid secretion, together with desquamated stratum corneum cells, constitutes the vernix caseosa.

APOCRINE GLANDS

The apocrine glands are located in the axillae, areolae, perianal, genital areas and the peri umbilical region. These large, coiled, tubular structures continuously secrete an odorless milky fluid that is discharged in response to adrenergic stimuli, usually as a result of emotional stress. Bacterial biotransformation of apocrine sweat components (fatty acids, thio alcohols and steroids) accounts for the unpleasant odour associated with perspiration. Apocrine glands remain dormant until puberty, when they enlarge and secretion begins in response to androgenic activity. The secretory coil of the gland consists of a single layer of cells enclosed by a layer of contractile myoepithelial cells. Although apocrine glands, do not function in thermo-regulation. They are involved in certain disease processes.

ECCRINE SWEAT GLANDS

Eccrine sweat glands are distributed over the entire body surface and are most abundant on the palms and soles. Those on the hairy skin respond to thermal stimuli and serve to regulate body temperature by delivering water to the skin surface for evaporation in contrast, sweat glands on the palms and soles, respond mainly to psychophysiologic stimuli.

Each eccrine gland consists of secretory coil located in the reticular dermis or subcutaneous fat and a secretory duct that opens onto the skin surface. The glands are supplied by sympathetic nerve fibers, but the pharmacologic mediator of sweating is acetylcholine rather than epinephrine. Sweat from these glands consists of water, sodium, potassium, calcium, chloride, phosphorus, lactate and small quantities of iron, glucose and protein. The composition varies with the rate of sweating but is always hypotonic in normal children.

NAILS

Nails are specialized protective epidermal structures that form convex translucent tight-fitting plates on the distal dorsal surfaces of the fingers and toes. The nail plate, which is derived from a metabolically active matrix of multiplying cells situated beneath the posterior nail fold, is composed of anucleate keratinocytes. Nail growth is relatively slow; complete finger nail regrowth takes 6 months, while complete toenail regrowth requires 12-18 months. The nail plate is bounded by the lateral and posterior nail folds; a thin eponychium(cuticle) protrudes from the posterior fold over a crescent-shaped white area called the lunula. The eponychium serves as a sealant barrier to protect the germinal matrix of the nail plate. Nail health relies on several factors, including nutrition, hydration, local infection/irritation and systemic disease.

BLOOD VESSELS

The cutaneous arteries arise directly or indirectly from the underlying source arteries forming anastomosis in the deepest part of the cortex. From here, single vessels run upwards and form a second network in the upper cortex. Finally teminal arterioles ascend into the papillae ending in capillary loops, which drain into connecting venules. The blood is returned to the large veins in the subcutaneous tissue.

LYMPHATICS

The skin contains a rich a network of lymphatics which drain into a few larger vessels in the hypodermis.

NERVE SUPLY

The nerve supply of skin consists of motor sympathetic portion derived from the symphathetic ganglia and sensory spinal portion arising from the dorsal root ganglia. The symphathetic fibre innervate the blood vessel, erector pilorum muscles and adrenergic and cause contraction.

FUNCTIONS OF THE SKIN

Protective function

The epidermis and sub cutaneous fat play roles in the protective functions, the mechanical properties of the skin depends mainly on the dermis. It forms an effective barrier against microbial invasion and has properties of mechanical, chemical, atomic, thermal and phototic damage.

Immunological function

The skin is a dynamic organ that contains different cells which contains elements of the innate and adaptive immune system which are activated when the tissue is under attack by invading pathogens

Sensory function

The skin is richly supplied with nerves. It has many nerve endings, which form the specialized cutaneous receptor which provide information regarding environmental changes to the brain.

Secretion function

Skin secretes sweat through sweat glands and sebum through sebaceous glands. By secreting sweat, skin regulates body temperature and water balance. Sebum keeps the skin smooth and moist.

Excretion function

Skin can excrete small quantities of waste materials like urea, salts and fatty substance.

Synthesis of vitamin-D

UV rays act on the skin to form Vit D3, activated in liver and kidneys, active form then acts on the intestines to increase calcium and phosphate absorption and on bone to increase calcium and phosphate mobilization.

Body heat regulation

Skin plays an important role in the regulation of body temperature. Excess heat is lost from body through skin by radiation, conduction, convection and evaporation. Sweat glands of the skin play active part in heat loss by secreting sweat. The lipid content of sebum prevents loss of heat from the body in cold environment.

Regulation of water and electrolyte balance

Skin regulates water balance and electrolyte balance by excreting water and salts through sweat.

Storage function of skin

Skin stores fat, water, chloride and sugar. It can also store blood by the dilatation of the cutaneous blood vessels

Absorption

Skin can absorb the fat soluble substances and some ointments

Gaseous exchange through skin

A small amount of gaseous exchange occurs through the skin, the amount of co_2 exchanged through the skin is negligible compared to the amount exhaled from the lungs.

Pigment of skin

Melanin pigment protects the skin from the harmful effects of ultraviolet rays.

ATOPIC DERMATITIS (or) ATOPIC ECZEMA

The signs and symptoms of "Bala karappan" are closely similar to signs and symptoms of Atopic Dermatitis (AD). Atopic dermatitis (AD) or eczema is the most common chronic relapsing skin disease seen in infancy and childhood. It affects 10-30% of the children worldwide and frequently occurs in families with other atopic disease such as asthma allergic rhinitis, and food allergy. Infants with Atopic dermatitis are predisposed to development of allergic rhinitis and asthma later in childhood. A process called "the atopic march".

DEFINITION

Atopic dermatitis is an inflammatory skin disorder characterized by erythema, edema, intense pruritis, exudation, crusting and scaling.

EPIDEMIOLOGY

The prevalence of Atopic dermatitis has increased over the past 30 years. It is currently estimated that 10-20% of children and 1-3% of adults in developed countries in within are affected by the disorder. Atopic dermatitis often starts in early infancy, approximately 45% of all cases begin within the first 6 months of life 60% during the first year and 85 % before 5 years of age upto 70% of these children outgrow the disorder before the adolescence. Children with atopic dermatitis are at high risk of

developing asthma and allergic rhinitis of those who will develop Atopic dermatitis before the age 2, 50% will develop asthma during subsequent years. The prevalence of eczema is on the increase and currently affects 12- 15% of all school age children.

Aetiology

Atopic dermatitis is a complex genetic disorder that results in a

- Defective skin barrier
- Reduced skin innate immune response
- Exaggerated T-cell response to environment allergens and microbes that lead to chronic skin inflammation.

Pathology

Acute Atopic dermatitis skin lesions are characterised by spongiosis or marked intercellular oedema of the epidermis. Antigen presenting cells (APCs) in the epidermis, such as langerhans cells (LCs) exhibit surface bound immunoglobulin (IgE) molecues.

These ACPs play an important role in cutaeous allergen presenting to T helper type 2 (Th2) cells. There is a marked perivenular T-cells infiltrate with occasional monocyte- macrophages in acute Atopic dermatitis lesions. Mast cells are found in normal numbers but in different stages of degranulation.

Chronic lichenified Atopic dermatitis is characterized by a hyperplasic epidermis with hyperkeratosis, and minimal spongiosis. There are predominantly IgE-bearing LCs in the epidermis, and macrophages in the dermis. Mast cell and eosinophil numbers are increased Eosinophil contribute to allergic inflammation by secreting cytokines and mediators that augment inflammatory responses and induce tissue injury in Atopic dermatitis through the production of reactive oxygen intermediates and release of toxic granule proteins.

Pathogenesis

Two forms of Atopic dermatitis have been identified

1) Atopic eczema is associated with IgE mediated sensitization and occurs in 70-80% of patients with Atopic dermatitis

2) Non atopic dermatitis is not associated with IgE mediated sensitization and is seen in 20-30% of patients with Atopic dermatitis. Both forms of Atopic dermatitis are associated with eosinophilia.

In atopic eczema circulating T cells expressing the skin homing receptor cutaneous lymphocyte – associated antigen (CLA) produced increased levels of the 2 cytokines, interleukin (IL-4) and another cytokine IL-5 plays an important role in eosinophil development.

Non atopic eczema is associated with lower IL-4 and IL-3 production than in atopic eczema. The developement of AD skin lesion is orchestrated by local tissue expression of pro inflammatory cytokines and chemokines. Cytokines such as tumour necrosis factor α (TNF-α) and IL -1 from keratinocytes, mast cells and dendritic cells bind the receptor on vasular endothelium.

These events proceed from tethering activation and adhesion to the endothelium, followed by extravasation of inflammatory cells. Once the inflammatory cells infiltrate the tissue, they respond to chemotactic gradients established by chemokines, released at sites of injury or infection. Chemokines plays a central role in defining the nature of the inflammatory infiltrate in Atopic dermatitis. Other c-c chemokines, monocytes, chemotactic protein -4 (MCP -4) exotaxin, macrophage-derived chemokines (MDC) are increased in Atopic dermatitis. Elevated IL-5 and GM/CSF of eosinophils and monocyte – macrophages as well as LCs.

In healthy people the skin acts as a protective barrier against external irritants, moisture loss and infection. Proper function of the skin depends on adequate moisture and lipid content, functional immune responses and structural integrity. Several dry-skin is a hallmark of atpoic dermatitis.

This is a result of compromise of physical and chemical structures of the epidermal barrier, which leads to excess transepidermal water loss. Filaggrin a component of the cytoskeleton and its breakdown products are critical to skin barrier function. Genetic mutations in the filaggrin gene family have been identified in up to 50% severe patients with Atopic dermatitis. Such patients have increased risk of bacterial, viral and fungal infection related to impairment of innate immunity, including a loss of barrier and impaired generation of antimicrobial peptides.

Potential Atopic dermatitis triggers:

Associated with food:

- Food allergens found in cow's milk, eggs, peanuts
- Tree nuts (eg. walnuts, cashews) Soya, wheat, fish, shelfish

Associated with direct contact

- Toiletries contacting alcohol, astringents, or fragrances harsh detergents/soaps
- Abrasive clothing (wool or synthetics)

Associated with physiologic /emotional stressor

- Infections (Especially from over heating/sweating)
- Psychological stress

Other factors

- Irritants - physical, chemical or electrical
- Sensitizers - plants, clothings, cosmetics, infections, diet and focal sepsis
- External infections - streptococci, staphylococci, fungus.
- Internal septic focus shedding toxins or causing bacteraemia.
- Diathesis - Allergic, xerodermic, hyperhidrotic or seborrhoeic
- Drugs - given for the diseaes or otherwise
- State of local or general nutrition
- Climate - Temperature and humidity

Clinical manifestations

Atopic dermatitis typically begins in infancy, 50% of patients experience symptoms in the 1 st yr of life & additional 30% all diagnosed between 1-5 yr of age.

Cardinal features of Atopic dermatitis are

In acute stage:

Intense pruritic with erythematic papular lesions.

In subacute stage:

Erythematous Excoriated, scaling papular lesion.

In chronic stage:

Lichenification or thickening of skin with accentuated surface markings and fibrotic papular (prurigo nodularis). In chronic Atopic dermatitis all three types of reactions may coexist in same individual.

Acute Atopic dermatitis in infants

- Extensor surface of extremities, face (forehead, cheeks)
- Neck, scalp, trunk

Chronic Atopic dermatitis in childhood (2 years to puberty)

- Flexual surface of extermities
- Neck, wrist, ankles

Clinical Features of Atopic dermatitis

Major features

- Pruritis, personal or family history of Atopic dermatitis
- Facial and extensor eczema in infants and children.
- Chronic or relapsing dermatitis

Associated Features

- Xerosis, keratosis, ichthyosis, palmar hyper linearity
- Cutaneous infections(staphylococcus, herpes simplex, moliuscum warts)
- Non specific dermatitis of the hands or feet
- White dermagraphism, Early age at onset
- Elevated serum Ig E levels, Facial erythema or pallor
- Positive results of immediate type allergy skin test
- Course influenced by environment \emotional factors

Lab Findings

- No specific Laboratory tests to diagnose Atopic dermatitis
- Peripheral blood eosinophilia
- Increased serum Ig E levels
- Prick skin test to identify the allergen.

Differential Diagnosis of Atopic Dermatitis

Infections and infestations

- Scabies, Dermatophytosis
- HIV associated dermatitis, Insect bites.

Congenital Disorders

- Familial keratosis pilaris
- Netherton syndrome

Chronic dermatomes

- Seborrheic dermatitis, contact dermatitis
- Nummular dermatitis
- Psoriasis dermatitis, ichthyosis dermatitis

Auto immune disorder

- Dermatitis herpetiformis
- Pemphigus foliaccus, Hyper IgE syndrome

Metabolic disorder

- Zinc deficiency, Pyridoxin, niacin, Phenyl ketonuria

TREATMENT

The Treatment of Atopic deramtitis requires a systematic multifaceted approach that incorporates – Skin hydration

Topical anti inflammatory therapy

Identification and elimination of flare factors

Systemic therapy

Categorization of physical severity of Atopic dermatitis

Clear - Normal skin with no evidence of Atopic dermatitis

Mild - Area of dry skin in frequent itching (with or without redness)

Moderate - Area of dry skin infrequent itching redness (with or without excoriation and localised skin thickening)

Severe - Widespread area of dry skin incessant itching, Redness (with or without excoriation, extensive skin thickening, bleeding, oozing, cracking and alteration of pigmentation)

Life style changes and general treatments for Atopic dermatitis

- Avoiding hot tubs, steam baths and chlorinated swimming pools
- Avoiding scratchy clothes, getting skin patch test
- Minimizing skin dryness by using lotion specifically designed for sensitive skin, drinking plenty of fluids

- Preventing flare- ups by avoiding exposure to the specific allergen or allergens that induce the condition
- Using ice bags or cool wet compresses to help relieve itching and inflammation, using mild soaps and not over harshly scrubbing skin.

Prick Test

Prick test are a way of detectimg cutaneous typr I (immediate) hypersensitivity to various antigens such as pollen, house dust mite or dander.

Patch test detect type IV (delayed or cell- mediated) hypersensitivity

It is common practice for a battery of around 20 common antigens, including common sensitizers such as nicke, rubber and fragrance mix to be applied to the skin of the back under aluminium discs for 48 hours. The sites are then examined for a positive reaction 24 hours later and again a further 2 hours later. The positive test is revealed by the development of an eczematous patch with erythematic swelling and vesicles at the site of application.

Patch Test reaction is graded in the following degrees

+ - Only redness

++ - Marked redness and swelling

+++ - Marked redness, swelling and papules

++++ - Redness, oedema and vesicles

Specific IgE levels to antigens can be measured in serum by a specific radio allergic sorbent test (RAST). These are occasionally performed to support diagnosis of Atopic eczema and to determine specific environment allergens, eg. Pet dander, horse hair, house dust mite, pollens and foods.

Bacterial and viral swabs for microscopy and culture

These are useful tests in suspected secondary infection. Skin swabs for bacteriology assessment will invariably reveal the presence of bacteria. In the case of recurrent impetigo in a child with atopic eczema, bacterial swabs should be taken from carrier sites (axillae and groin) from both the affected individual and house hold members.

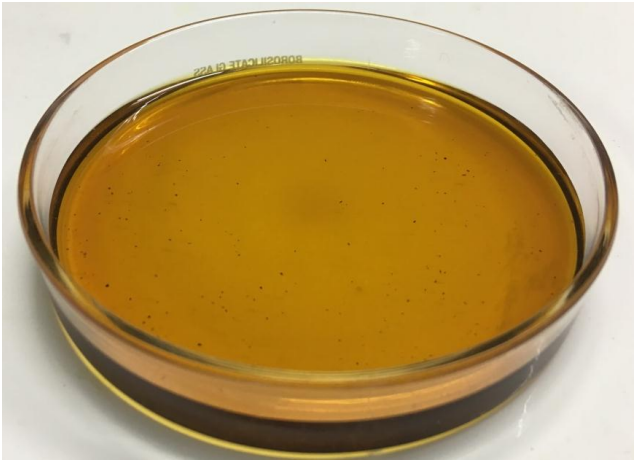
Prognosis of Atopic dermatitis

Dermatitis and Eczema are as rule curable conditions. Dermatitis is mostly non-infective and they do not leave scars. The patient needs reassurance of these points. It must be remembered that epidermis is an ectodermic structure and so takes time to heal.

Acute eczema heals readly in about 1-4 weeks with treatment. Chronic eczemas in which anatomical and functional changes set in, take time to disappear. Disseminated and generalised eczemas are not only slow to heal, but are accompanined by ill health.

Infantile and Atopic eczema are troublesome and uncomfortable. The former lates till the age of twenty five or even though life. Its course is marked by spontaneous remissions and exacerbations. Psychogenic stresses, climate extremes and poor health aggravate eczema. The cure of these conditions is restarted in tropical countries by heat, humidity and the prevalent unhygienic condition.

TRIAL DRUG – SAARANAI ENNAI



Saaranai ennai (SE)

சாரணை எண்ணெய்

"சாரணை யூத்தா மணிவேருந்
தானே கிளரு முடக்கொத்தான்
வாரணி சிறிய வழுதலைவேர்
மெருக்கு முருங்கைபுங்கு
வேருடன் கொடிக்கழல் மிளகுள்ளி
மிகுத்த பூதக் கரப்பானுங்
கூரணி வசம்புஞ் சமனாகக்
கொண்டா மணக்கெண்ணெயிற் கெந்தித்தே
பதத்தில் வடித்து உள்ளுக்குக் கொடுத்து
மேலும் பூசவும்".

Usage : Internal and external medcine

Ref : Pillaipini Maruthuvam, Pg.no: 522, 571

Author: A.Sundarasan,B.I.M.

SOURCE OF RAW DRUGS:

The drug Uthamani ver, mudakothan ver, siria Vazhuthalai ver, Yerukku ver, murungai ver, pungan ver was collected from my native place, Thiruvannamalai. And other required raw drug were procured from a well reputed indigenous drug shop from Paris town, Chennai. All raw drugs were Authenticated by the Pharmacognosist, Department of Medicinal Botany, GSMC, Chennai.

PURIFICATION OF RAW DRUGS:

Raw drugs are purified as mentioned in *Sikicharathna deepam sarakku suthi muraigal*.

INGREDIENTS:

1. Saaranai ver (*Trianthema decandra*)
2. Uthamani ver (*Pergularia daemia*)
3. Mudakothan ver (*Cardiospermum halicacabum*)
4. Siria vazhuthalai ver (*Solanum melongena*)
5. Yerukku ver (*Calotrophia gigantia*)
6. Murungai ver (*Moringa olifera*)
7. Pungan ver (*Pongamia pinnata*)
8. Kalarchi (*Caesalpinia bonduc*)
9. Milagu (*Piper nigrum*)
10. Ulli (*Allium sativum*)
11. Bootha karappan pattai (*Sterculia foetida*)
12. Vasambu (*Acorus calamus*)
13. Amanakku ennai (*Ricinus communis*)

TRIAL MEDICINE INGREDIENTS

Pergularia daemia

Ricinus communis

Caesalpinia bonduc

Acorus calamus

Solanum melongena

Allium sativum

Cardiospermum halicacabum

Pongamia pinnata

Trianthema decandra

Calotrophia gigantia

Piper nigrum

Moringa olifera

Sterculia foetida

PREPARATION AND PROPERTIES OF TRIAL DRUGS

METHOD OF PREPARATION

PREPARATION:

All the above drugs were purified. The purified drugs were made into fine powder, ground with water and made into paste. The paste was mixed with the castor oil and allowed to boil until it reaches the manal patham for external and mezhugu patham for internal medicine.

DRUG STORAGE:

The trial drug saaranai ennai stored in air tight container internally and externally separately. And it is dispensed to the patients.

Dosage - Internally : 1-2ml
Externally : 30ml

Duration - 21 days

Indication - Karappan

PROPERTIES OF TRIAL DRUG:

1. **SAARANAI VER**

Botanical name : *Trianthema decandra*

English name : Spreading hog weeds

Family : Aizoaceae

Organoleptic characters

Taste : Kaippu

Potency : Veppam

Division : Karppu

Chemical constituents : Trianthimine flavonoid, Alkaloid, Tetraterpenoid.

Action : Expectorant, Laxative, Anti – microbial, Anti-histamine.

Pothu gunam

“சீதஞ் சலதோடந் தேமல்த ழும்புகுன்மம்
வாதஞ் சிறுசிரங் வன்மேகம் – ஓதரிய
காசமுதல் நோயெல்லாங் கான்சா றடைக்கிழங்கால்
நாசமுறு மென்றே நவில்”.

2. UTHTHAMANI VER

Botanical name : *Pergularia daemia*

English name : Dog's bane white low plant

Family : Asclepidaceae

Organoleptic characters

Taste : Kaippu

Potency : Veppam

Division : Karppu

Chemical constituents : Saponin, Steroid, Alkaloids, Triterpenes, Cardenolides, Carbohydrates.

Action : Anthelmintic, Anti-inflammatory, Anti-bacterial, Anti-fungal

Pothu gunam

"உத்தா மணியிலையால் உள்வயிற்றுக் குன்மமோடு
குத்தாம் வலியுங் குளிரும்போம் பற்றி
இசிக்கும் வலியிரைப்பு எத்தடிப்பும் ஏகும்
பசிக்குமதி மாந்தமும்போம் பார்".

-அகத்தியர் குணவாகடம்

3. MUDAKKOTHTHAAN VER

Botanical name : *Cardiospermum halicacabum*

English name : Ballon vine; Heart pea or Winter cherry

Family : Sapindaceae

Organoleptic characters

Taste : Kaippu

Potency : Thatpam

Division : Kaarppu

Chemical constituent : Calycosin, Guercetin, Hentriacontunol, Saponin, Essential oil, Rutin, Apigenin, Protocatchuic acid, Pentadecanoie acid, Protocatechualdehyde.

Action : Anti – inflammatory, Anti – oxidant, Laxative, Stomachic.

Pothu gunam

“சூலைப் பிடிப்பு சொறி சிரங்கு வங்கரப்பான்
காலைத் தொடுவாய்வுங் கன்மலமும் – சாலக்
கடக்கத்தா னோடிவிடுங் காசினியை விட்டு
முடக்கற்றான் றன்னை மொழி”.

4. SIRIYA VAZHUTHALAI VER

Botanical name	**:**	*Solanum melongena*
English name	**:**	Eggplant, Brinjal
Family	**:**	Solanaceae
Organoleptic characters		
Taste	**:**	Kaippu, Thuvarppu
Potency	**:**	Veppam
Division	**:**	Kaarppu
Chemical constituents	**:**	Flavonoids, Tannins, Glycosides, Steroids, Alkalods, Saponin.
Action	**:**	Anti-inflammatory, Anti-oxidant, Stimulant, Hypnotic, Expectorant.

Pothu gunam

“வழுதலை யாகிய வங்கக் காய்தினப்
பழுதிலை யஃதுநந் பத்திய மாகுமே”.

-தேரையர் காப்பியம்

“எக்கால மும்பழகி யில்லாத மானிடர்க்கு
முக்கால முண்டாலும் மோசமிரா – பக்குவமா
யங்கந் தணிய வமாபத்தி யக்கறியாம்
வங்கக்கா யுண்டறிடு வாய்”.

-தேரன் வெண்பா

5. ERUKKU VER

Botanical name : *Calotropis gigantea*

English name : Mudar, Gigantic swallow wood

Family : Asclepidaceae

Organoleptic characters

Taste : Kaippu, kaarppu, madhuram

Potency : Veppam

Division : Kaarppu

Chemical constituents : Methyl-β-carboline, carboxylate, dehydrovomifoliol, pleurone, calotropogenin, calotoxin, giganteol.

Action : Anthelmentic, stimulant, tonic, diaphoretic, febrifuge, emetic, alterative, laxative, Anti-histamine, Anti-microbial

Pothu gunam

"மன்னனையுங் கையெடுக்க வைத்தெயிற்று னேயகற்றி
யுன்னு பிணிப்பணியை யோட்டுதலாற் – சொன்னேன்
எருக்கெனவே பூமி யினிலே விளங்கும்
அருக்கு மருக்கனென லாம்".

-தேரன் வெண்பா

6. MURUNGAI VER

Botanical name : *Moringa oleifera*

English name : Horse radish, drum stick tree

Family : Moringaceae

Organoleptic characters

Taste : Kaippu, thuvarppu, inippu

Potency : Thatpam

Division : Kaarppu

Chemical constituents : White Crystalline Alkaloids, Myristic Acid, Mucilage, Gum resins, Phytosterol, Moringine.

Action : Stimulant, Expectorant, Diuretic, Antispasmodic, Tonic, Anti –inflammatory, anti-histamine.

Pothu gunam

"தின்றாற் கசப்பாகும் தீயாய் கொடுவிடத்தைக்
கொன்றுவிடும் கட்குங் குளிர்ச்சிதரும் – என்னுமையம்
ஒட்டும்வேர் பூவிலைகாய் உற்றபசி னும்பிஞ்சுங்
காட்டுப் புன்முருங்கை காண்".

-அகத்தியர் குணவாகடம்

"முருங்கைக் காய்க்கறி முகிளிலை வேர்கொன
வொருங்குள நோயெலா மோவுந் துற்ததும்".

-தேரன் காப்பியம்

7. PUNGAN VER

Botanical name : *Pongamia pinnata*

English name : Karanka

Family : Papilionaceae

Organoleptic characters

Taste : Kaippu, thuvarppu

Potency : Veppam

Division : Kaarppu

Chemical constituents : Pongamol, Pongagalabrone, Pinnatin, Pongapin.

Action : Astringent, Alterative parasiticide, Antiseptic, Stimulant, Anti – inflammatory.

Pothu gunam

"வாதக் கடுப்பு மகாமூர்ச்சை தாபசுரம்
வாதகுன்மம் ரத்தத்தால் வந்திடுநோய் – ஓதுகின்ற
பண்புரையும் வல்விடமும் போகும் திரண்டருண்டே
பண்புறுபுங் கம்வேர்க்குப் பார்".

8. KAZHARCHI

Botanical name : *Caesalpinia bonduc*

English name : Bonduc nut, physic nut, moloucca bead.

Family : Fabaceae

Organoleptic characters

Taste : Kaippu

Potency : Veppam

Division : Kaarppu

Chemical constituents : Homoisoflavanoids, Caesalpinianone, 6-0-methylcaesalpinianone, Glutathione- s – transferase.

Action Antiperiodic, Antispasmodic, Tonic, Anthelmintic, Febrifuge, Deobstructent, Anti – Oxidant, Anti-Microbial.

Pothu gunam

"கோசஞ் சுருங்கக் குடிலமிகு மன்னவனால்
வீசஞ் சுருங்காது மேலட்ட - மோசம்
ஒழிய மருந்தாகி யொத்தாசை செய்யும்
கழலா கியகழற்சிக் காய்".

9. MILAGU

Botanical name : *Piper nigrum*

English name : Black pepper

Family : Piperaceae

Organoleptic characters

Taste : Kaippu, kaarppu

Potency : Veppam

Division : Kaarppu

Chemical constituents : Alkaloids, Chavicine, Piperine, Piperidine, Piperetin, Volatile oil, Caryophyllene.

Action : Acrid, Carminative, Antiperiodic, Stimulent, Resolvent, Antivatha, Antidote, Anti – histamine, Anti –oxidant, Anti- bacterial.

Pothu gunam

"தீயாகி யெங்கும் திரியுமதை யாவத்து
மோயாம லெப்படியு முண்டாக்காற் - பாயாது
போந்திமிர்வா தங்கிரந்தி புண்ணீரும் மண்ணவர்க்கும்
காந்திமெய்வா தச்சலுப்பைக் காய்".

-தேரன் வெண்பா

10. ULLI

Botanical name : *Allium sativum*
English name : Garlic
Family : Liliaceae
Organoleptic characters
Taste : Kaarppu
Potency : Veppam
Division : Kaarppu
Chemical constituents : Allixin, Methyl allyl disulphide, S-allyl cysteine, Alliin, Allicin
Action : Carminative, Stomachic, Tonic, Alterative, Stimulant, Expectorant, Diuretic, Anthelmintic, Anti – histamine, Anti-microbial

Pothu gunam

சன்னியொடு வாதந் தலைதோவு தாள்வலி
மன்னிவரு நீர்கோவை வன்சீதம் - அன்னமே!
உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளி தன்னால் வெருண்டு.

11. BOOTHAKARAPPAAN PATTAI

Botanical name : *Sterculia foetida*
English name : Poon tree, pinari
Family : Sterculiaceae

Organoleptic characters

Taste	**:**	Kaippu
Potency	**:**	Veppam
Division	**:**	Kaarppu
Chemical constituents	**:**	Flavanoids, Phenylpropanoids, Alkaloids, Terpenoids
Action	**:**	Laxative, Diuretics, Diaphoretic, Anti – inflammatory, Anti- Histamine

Pothu gunam

பெருமரப் பட்டையது பேதி கிராணி
மருவிரத்த நோயினத்தை மாற்றுந் - திருவே
நடலைபுரி வாதத்தை நாடாத கற்றும்
உடலையிரட் சிக்குமென வோது.

-அகத்தியர் குணவாகடம்

12. <u>VASAMBU</u>

Botanical name	**:**	*Acorus calamus*
English name	**:**	Sweet-Flag
Family	**:**	Araceae

Organoleptic characters

Taste	**:**	Kaarppu
Potency	**:**	Veppam
Division	**:**	Kaarppu
Chemical constituents	**:**	Acorin, Calamin, Steroids, Glycosides
Action	**:**	Stimulant, Stomachic, Anti pesticide, Carminative, Diuretic, Disinfectant, Germicide, Anti –inflammatory

Pothu gunam

பாம்பாதி நஞ்சற் புதப்புண் வலிவிடபாகங் குண்மம்
சூம்பா ரிரத்தபித் தம்முக நாற்றம்வன் சூலைசன்னி
வீம்பான்பை காசம் பீலீகஞ் சிலிபதம் வீறிருமல்
தாம்பாங் கிருமி யிவையேகு மாசிவ சம்பினையெ

-தேரன் குணவாகடம்

13. AAMANAKKU

Botanical name : *Ricinus communis*

English name : Castor-oil plant.

Family : Euphorbiaceae

Organoleptic characters

Taste : Kaippu

Potency : Veppam

Division : Kaarppu

Chemical constituents : Glycerides, Ricinoleic, isoricinoleic, dihydrocystearic acids, lipases, alkaloid, ricine

Action : Laxative, Emollient, Antivatha, Laxative, Stimulant, Anti inflammatory

Pothu gunam

யேரண்டத்துநெய் யென்பது டற்கொடு
சிரண்டத்தணி செய்திடு நிசமே.

-தேரன் காப்பியம்

ஆமணக்கு நெய்யால் நலமுண்டாம் யாவர்க்கும்
பூமணக்கு மேனி புரிகுழலே - வாய்மணக்கக்
கொள்ளில் வயிறுவிடுங் கோரமுள்ள வாயுவுறும்
உள்ளில்வரு குன்மம்போ மோது

-அகத்தியர் குணவாகடம்

PRE-CLINICAL SAFETY STUDIES

BIO CHEMICAL ANALYSIS

Preparation of sodium carbonate extract

2 gm of *Saaranai ennai* sample is mixed with 5gm of sodium carbonate and taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called sodium carbonate extract.

S. No.	EXPERIMENT	OBSERVATION	INFERENCE
TEST FOR ACID RADICALS			
1. A.	**Test for sulphate:** 2ml of the above prepared extract is taken in a test tube.to this add 2ml of 4% Ammonium oxalate solution.	Absence of white precipitate	Absent
B.	2ml of extract is added with 2ml of dilute Hydrochloric acid until the effervescence ceases off. Then 2ml Barium chloride solution is added.	Absence of white precipitate	Absent
2.	**Test for chloride :** 2ml of extract is added with dilute Nitric acid till the effervescence ceases. Then 2ml of silver nitrate solution is added.	Presence of white precipitate	Present
3.	**Test for phosphate:** 2 ml of the extract is treated with 2 ml of Ammonium molybdate solution and 2 ml of concentrated nitric acid.	Absence of Yellow precipitate	Absent
4.	**Test for carbonate:** 2 ml of the extract is treated with 2 ml of Magnesium sulphate solution.	Absence of white precipitate	Absent
5.	**Test for sulphide:** 1 gm of the substance is treated with 2 ml of concentrated Hydrochloric acid.	Absence of Rotten egg smelling	Absent

6.	**Test for Fluoride and oxalate :** 2ml of extract is added with dilute Acetic acid and 2 ml of Calcium chloride solution and heated.	Absence of white precipitate	Absent
7.	**Test for Borate :** 2 pinches of the substance is made into paste by using Sulphuric acid and alcohol (95%) and introduced into the blue flame.	Absence of Green tinged flame	Absent
TEST FOR BASIC RADICALS			
8.	**Test for lead:** 2 ml of the extract is added with 2 ml of Potassium iodide solution.	Absence of Yellow precipitate	Absent
9.	**Test for copper:** One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the non-luminous part of the flame.	Absence of Bluish green colored flame	Absent
10.	**Test for aluminium:** To the 2 ml of extract Sodium hydroxide solution is added in drops in excess.	Absence of white precipitate	Absent
11.	**Test for iron:** To the 2 ml of extract 2ml of Ammonium thiocyanate solution and 2ml of concentrated Nitric acid is added.	Presence of Blood red colour	Present
12.	**Test for zinc:** To the 2 ml of extract Sodium hydroxide solution is added in drops in excess.	Absence of green tinged flame.	Absent
13.	**Test for calcium:** To the 2 ml of extract Ammonium oxalate solution solution is added.	Absence of white precipitate	Absent

14.	**Test for magnesium:** To the 2 ml of extract Sodium hydroxide solution is added in drops in excess.	Absence of white precipitate	Absent
15.	**Test for ammonium:** To the 2 ml of extract few ml of Nessler's reagent and excess of Sodium hydroxide solution are added.	Absence of white precipitate	Absent
16.	**Test for sodium:** 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame	Absence of white precipitate	Absent
17.	**Test for mercury:** 2 ml of extract is treated with 2ml of Sodium hydroxide solution.	Absence of Yellow precipitate	Absent
18.	**Test for arsenic:** 2 ml of extract is treated with 2ml of Silver nitrate solution.	Absence of white precipitate	Absent
19.	**Test for starch:** 2 ml of extracts treated with weak iodine solution.	Absence of white precipitate	Absent
20.	**Test for reducing sugar** 5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2minutes.The colour changes are noted.	Absence of white precipitate	Absent
21.	**Test for alkaloids :** 2 ml of the extract is treated with 2ml of Potassium iodide solution.	Absence of white precipitate	Absent

RESULT

The given sample *Saaranai ennai* contains **Chloride, Iron**

PHYTOCHEMICAL ANALYSIS

Project Report

Project ID	**NRS/AS/0338/02/2019**
Name and Address of the Researcher	**Dr.T.Swathini** **Government Siddha Medical College, Chennai** **Tamil Nadu, India**
Sample –ID	**SaaranaiEnnai - SE**

PHYTOCHEMICAL ANALYSIS

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for coumarins:

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for saponins:

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for tannins:

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for flavonoids:

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols:

Lead acetate test: To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids:

To the test sample, 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Triterpenoids

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins

A. Aanthocyanin:

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100^{o}C. Formation of bluish green colour indicates the presence of anthocyanin.

Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

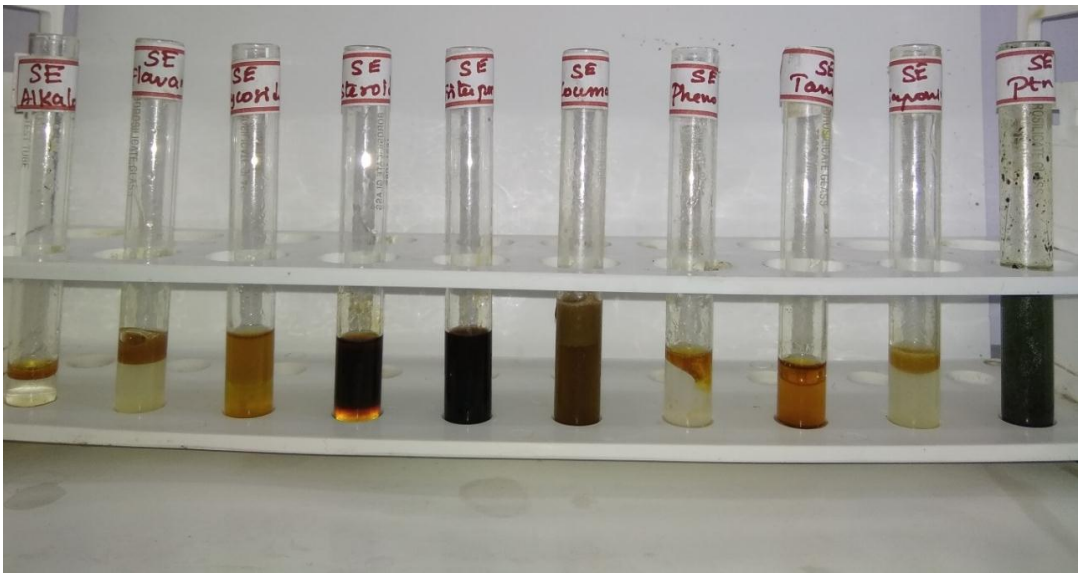
Proteins (Biuret Test)

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

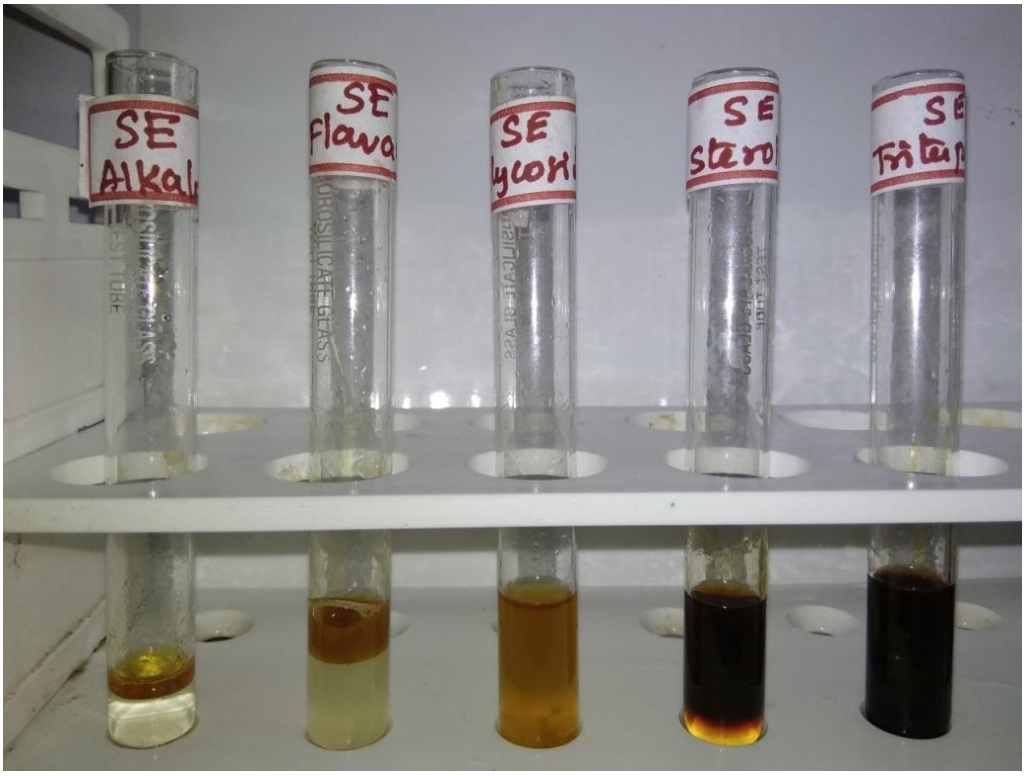
Reference

Brain KR, Turner TD. The Practical Evaluation of Phytopharmaceuticals. Bristol: Wright Scientechnica; 1975:36-45

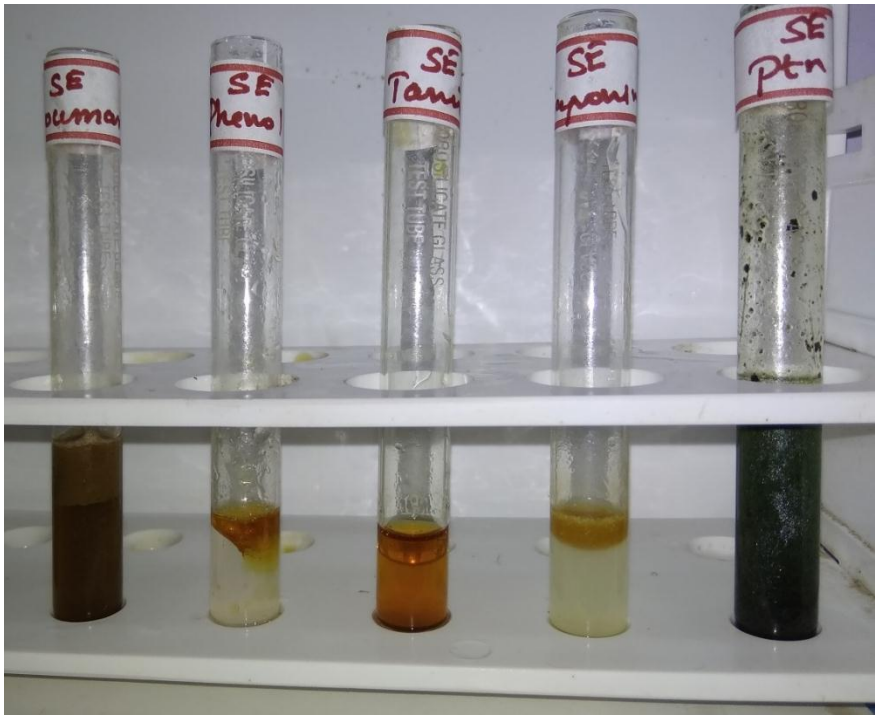
RESULTS



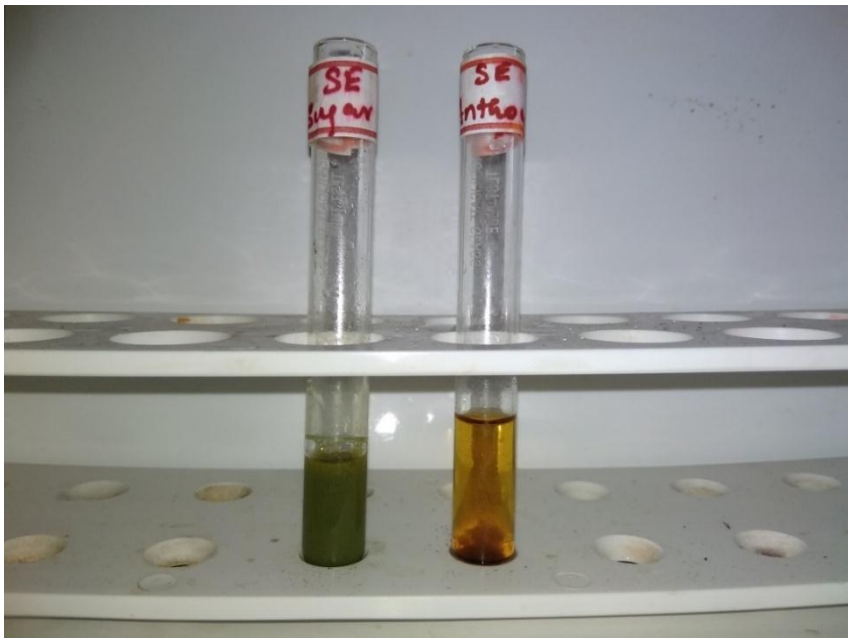
Test for Alkaloids, Flavonoids, Glycosides, Steroids and Triterpenoids



Test for Coumarins, Phenol, Tanins, Saponin and Protein



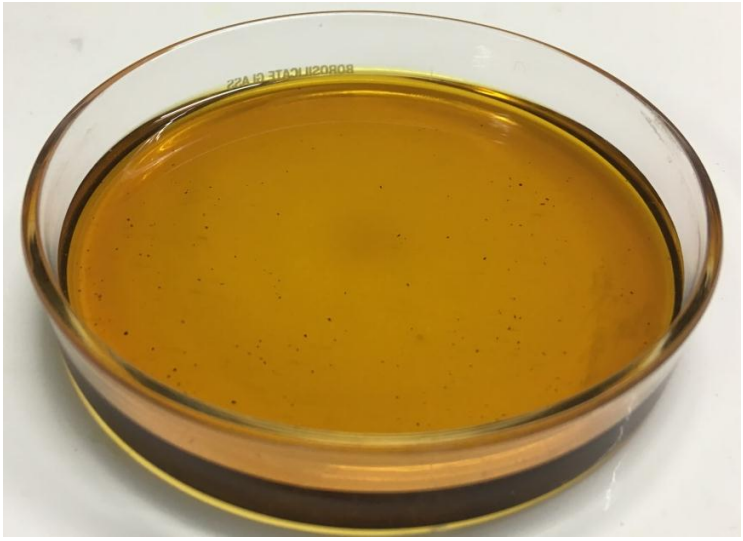
Test for Cyanin and carbohydrates



PHYSICOCHEMICAL EVALUATION REPORT

Project ID	**NRS/AS/0338/02/2019**
Name and Address of the Researcher	**Dr.T.Swathini** **Government Siddha Medical College, Chennai** **Tamil Nadu, India**
Sample –ID	**SaaranaiEnnai – SE**

Sample Description



State	Liquid
Appearance	Reddish Brown
Odour	Aromatic
Nature	Dense viscous

Determination of Iodine value

About 20 gm of test sample was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed

by this about 25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for anhour.T About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2 gm of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeatthe same procedure with out taking the sample for blank titration . Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

Determination of Viscosity value

Viscosity determination were been carried out using Ostwald viscometers. Measurement of viscosity involves thedetermination of the time required for a given volume ofliquid to flow through a capillary.The liquid is added to the viscometer, pulled into the upper reservoir by suction, and then allowed to drain by gravity back into the lower reservoir. The time that it takes for the liquid to pass between twoetched marks, one above and one bellow the upper reservoir, is measured.

Determination of Refractive Index

Determination of RL was carried out using Refractometer.

Determination of Weight per ml

Weight per ml was determined using the comparative weight calibration method, in which the weight of 1ml of the base of the formulation was calculated and then weight of 1 ml of finished formulation were been calculated. The difference between weight variations of the base with respect to finished formulation calculated as an index of weight per ml.

Acid Value

Accurately 5 g of test sample was weighed and transferred into a 250 mL conical flask. To this, a 50 mL of neutralized alcohol solution was added. This mixture was heated for 10 min by heating mantle. Afterwards, the solution was taken out after 10 min and 1 or 2 drops of phenolphthalein indicator was added. This

solution was titrated against KOH solution from the burette. The appearance of pink color indicated the end point. The volume of consumed KOH solution was determined and the titration of test sample was carried out in triplicate and the mean of the successive readings was used to calculate the acid-value of the respective sample by following expression.

Acid value = Titter Value X 0.00561X 1000 / Wt of test sample (g)

Peroxide value

5 g of the substance being examined, accurately weighed, into a 250-ml glass-stoppered conical flask, add 30 ml of a mixture of 3 volumes of glacial acetic acid and 2 volumes of chloroform, swirl until dissolved and add 0.5ml volumes of saturated potassium iodide soluton. Allow to stand for exactly 1 minute, with occasional shaking, add 30 ml of water and titrate gradually, with continuous and vigorous shaking, with 0.01M sodium thiosulphate until the yellow colour almost disappears. Add 0.5 ml of starch solution and continue the titration, shaking vigorously until the blue colour just disappears (a ml). Repeat the operation omitting the substance being examined (b ml). The volume of 0.01M sodium thiosulphate in the blank determination must not exceed 0.1 ml.

Analytical Report

S.NO	*PARAMETER*	*SE*
1	***Viscosity at 50^{o}C (Pa s)***	*77.17*
2	***Refractive index***	*1.32*
3	***Weight per ml (gm/ml)***	*0.087 gm/ml*
4	***Iodoine value (mg I2/g)***	*95.25*
5	***Saponification Value (mg of KOH to saponify 1gm of fat)***	*174.8*
6	***Acid Value mg KOH/g***	*1.047*
7	***Peroxidase Value mEq/kg***	*4.987*

TLC Analysis

Test sample was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with the specified solvent system After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm.

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of phytotherapeutics.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analyzed. After elution, plates were taken out of the chamber and dried.

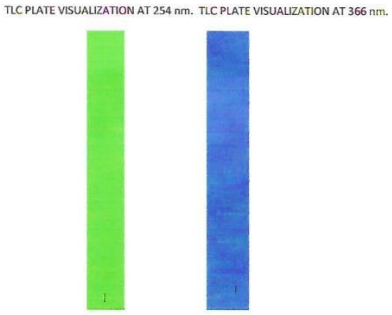
Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each sample and their respective Rf values were tabulated.

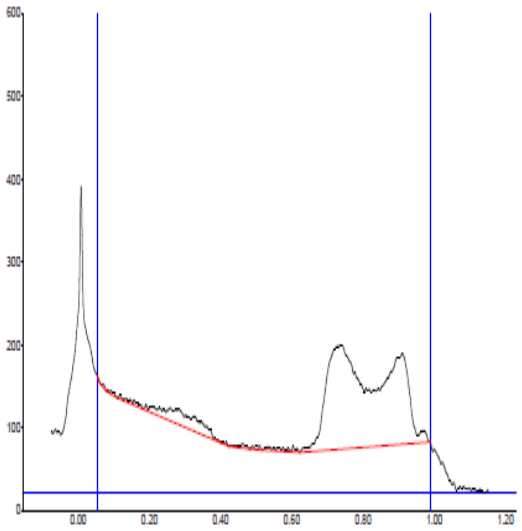
HPTLC ANALYSIS

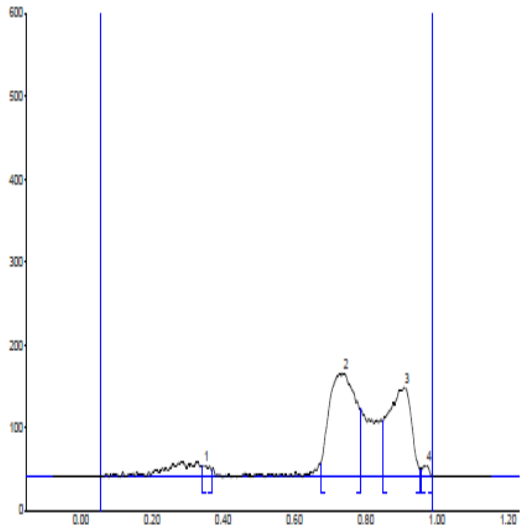
Project ID	NRS/AS/0338/02/2019
Name and Address of the Researcher	Dr.T.Swathini Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	HPTLC Analysis
Sample Received	In Person
Sample –ID	SaaranaiEnnai - SE
Method of Analysis **Instrument** **TLC Plate Mobile Phase**	CAMAG TLC SCANNER III Aluminium Coated Silica Gel – Merck Chloroform: n-Butanol: Methanol: Water: Acetic Acid (4:1:1:0.5:0.5)
Analysis Type	Third Party Analysis
Date of Analysis	4/3/2019
Result of Analysis	Test Report Attached as Annexure

TLC



HPTLC finger printing of Sample SE





Peak Table

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.34	13.2	0.35	15.6	5.85	0.37	9.0	227.7	1.79
2	0.67	16.9	0.74	126.1	47.33	0.79	82.8	7053.2	55.29
3	0.85	68.3	0.91	109.7	41.16	0.95	9.8	5274.7	41.35
4	0.96	9.7	0.97	15.1	5.66	0.99	0.8	202.1	1.58

REPORT

HPTLC finger printing analysis of the sample reveals the presence of four prominent peaks corresponds to presence of four versatile phytocomponents present with in it. R fvalue of the peaks ranges from 0.34 to 0.96. Further the peak 2 and 3 occupies the major percentage of area of 55.29 and 41.35% which denotes the abundant existence of such compound.

TEST FOR SPECIFIC PATHOGEN

Methodology

Test sample was directly inoculated in to the specific pathogen medium (EMB, DCC, Mannitol, Cetrimide) by pour plate method. The plates were incubated at 37^{o}C for 24 - 72h for observation. Presence of specific pathogen identified by their characteristic color with respect to pattern of colony formation in each differential media.

Detail of Specific Medium and their abbreviation

Organism	**Abbreviation**	**Medium**
E-coli	***EC***	***EMB Agar***
Salmonella	***SA***	***Deoxycholate agar***
Staphylococcus Aureus	***ST***	***Mannitol salt agar***
Pseudomonas Aeruginosa	***PS***	***Cetrimide Agar***

Observation

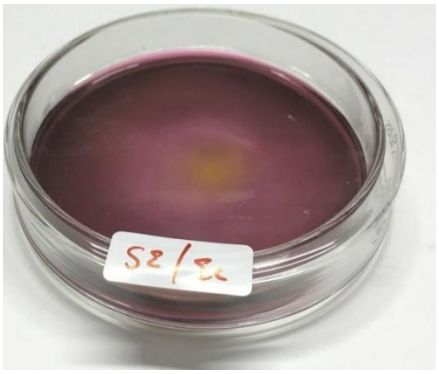
No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

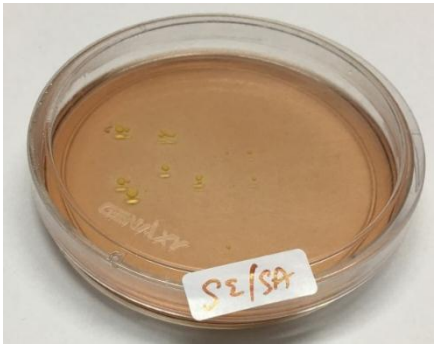
No growth / colonies were observed in any of the plates inoculated with the test sample.

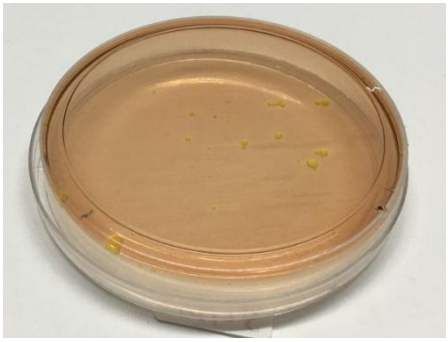
Organism	**Specification**	**Result**	**Method**
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

Culture plate with E-coli (EC) specific medium

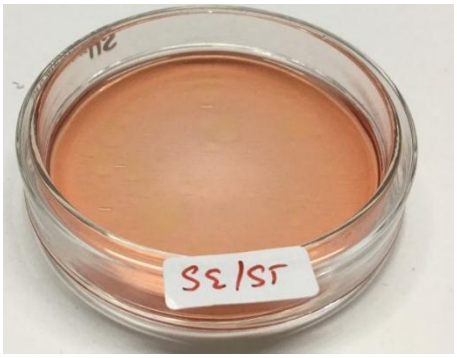


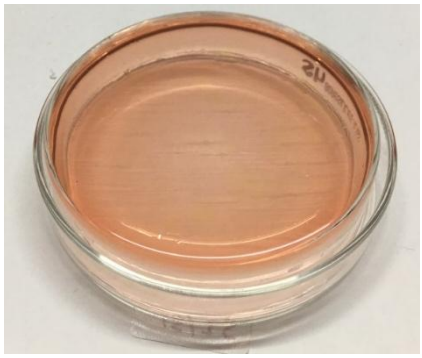
Culture plate with Salmonella (SA) specific medium



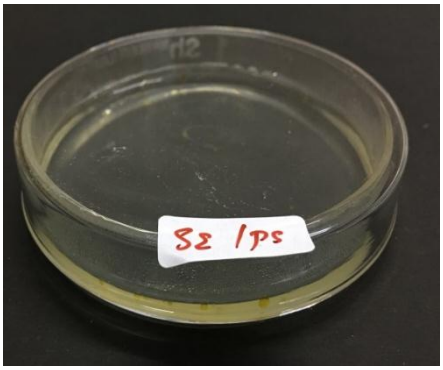


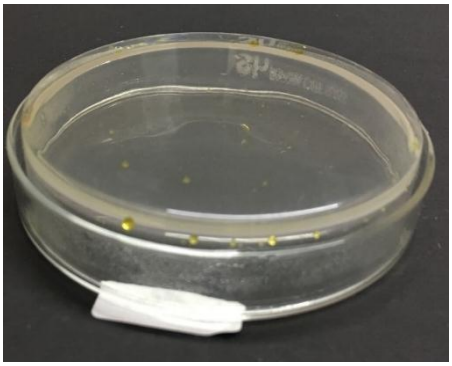
Cullture plate with Staphylococcus Aureus (ST) specific medium





Culture plate with Pseudomonas Aeruginosa (PS) specific medium





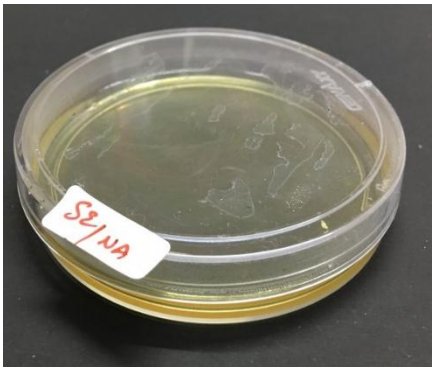
STERILITY TEST BY POUR PLATE METHOD

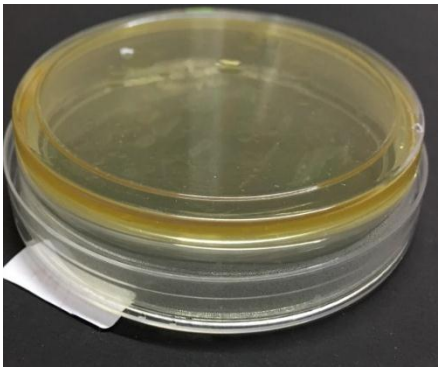
Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated / un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Methodology

Test sample was admixed with sterile distilled water and the mixture were been used for the sterility evaluation. About 1ml of the test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45^{o}C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37^{o} C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.





Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

No growth / colonies were observed in any of the plates inoculates with the test sample.

Test	**Result**	**Specification**	**As per AYUSH/WHO**
Total Bacterial Count	Absent	NMT 10^{5}CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^{3}CFU/g	

HEAVY METAL ANALYSIS

Project ID	NRS/AS/0338/02/2019
Name and Address of the Researcher	Dr.T.Swathini Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	Heavy Metal analysis by AAS
Sample Received	In Person
Sample –ID	SaaranaiEnnai - SE
Description of the Sample	Liquid
Method of Analysis Instrument **Extraction Solvent**	Model: AA 240 Series HCl and HNO3
Analysis Type	Third Party Analysis
Date of Analysis	14/3/2019
Result of Analysis	Test Report Attached as Annexure

HEAVY METAL ANALYSIS BY AAS

Standard: Hg, As, Pb and Cd – Sigma

Methodology

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test item.

Sample Digestion

Test sample was digested with 1mol/L HCl for determination of arsenic and mercury. Similarly for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3.

Standard reparation

As & Hg- 100 ppm sample in 1mol/L HClCd &Pb- 100 ppm sample in 1mol/L HNO_3

Test Report

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis	Maximum Limit
Mercury	253.7 nm	BDL	1 ppm
Lead	217.0 nm	BDL	10 ppm
Arsenic	193.7 nm	BDL	3 ppm
Cadmium	228.8 nm	BDL	0.3 ppm

BDL- Below Detection Limit

Report and Inference

Results of the present investigation have clearly shows that the sample has no traces of heavy metals such as Mercury, Arsenic, Cadmium andLead.

AFLATOXIN ANALYSIS

Project ID	NRS/AS/0338/02/2019
Name and Address of the Researcher	Dr.T.Swathini GovernmentSiddhaMedicalCollege ,Chennai Tamil Nadu,India
Parameter Requested by the Customer for Analysis	Aflatoxin Assay By TLC (B1,B2,G1,G2)
Sample Received	In person
Sample –ID	Saaranai Ennai - SE
Description of the Sample	Liquid
Analysis Type	Third Party Analysis
Date of Analysis	14/03/2019
Result of Analysis	Test Report Attached

Strandard

Aflatoxin B1
Aflatoxin B2
Aflatoxin G1
Aflatoxin G2..

Solvent

Standard samples was dissolved in a mixture of chloroform and acetonitrile (9.8 : 0.2) to obtain a solution having concentrations of 0.5 µg per ml each of aflatoxin B1 and aflatoxin G1 and 0.1 µg per ml each of aflatoxin B2 and aflatoxin G2.

Test solution: Concentration 1 µg per ml

Procedure

Standard aflatoxin was applied on to the surface to pre coated TLC plate in the volume of2.5 µL, 5µL, 7.5 µL and 10 µL. Similarly the test sample was placed and Allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of chloroform, acetone and isopropyl alcohol (85 : 10 : 5) until the solvent front has moved not less than 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent from and allow the plate to air-dry. Locate the spots on the plate by examination under UV light at 365 nm.

Aflatoxin	Sample SE	AYUSH Specification Limit
B1	Not Detected - Absent	0.5 ppm
B2	Not Detected - Absent	0.1 ppm
G1	Not Detected - Absent	0.5 ppm
G2	Not Detected - Absent	0.1 ppm

Result:

The results shown that there was no spots were been identified in the test sample loaded on TLC plates when compare to the standard , which indicates that the sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2.

Reference

Luciana de CASTRO. Determining Aflatoxins B1, B2, G1 And G2 In Maize Using Florisil Clean Up With Thin Layer Chromatography And Visual And Densitometric Quantification. Ciênc. Tecnol. Aliment. vol.21 no.1 Campinas. 2001.

ACUTE ORAL TOXICITY STUDY OF *SAARANAI ENNAI*
(OECD GUIDELINE – 423)

Introduction:

- The acute toxic class method is a stepwise procedure with the use of 3 animals of a single sex per step.
- Depending on the mortality and/or the moribund status of the animals, on average 2-4 steps may be necessary to allow judgement on the acute toxicity of the test substance.
- This procedure is reproducible, uses very few animals and is able to rank substances in a similar manner to the other acute toxicity testing methods.
- The acute toxic class method is based on biometric evaluations with fixed doses, adequately separated to enable a substance to be ranked for classification purposes and hazard assessment.
- In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.
- The method allows for the determination of an LD50 value only when at least two doses result in mortality higher than 0% and lower than 100%.
- The use of a selection of pre-defined doses, regardless of test substance, with classification explicitly tied to number of animals observed in different states improves the opportunity for laboratory to laboratory reporting consistency and repeatability.

Principle of the Test:

It is the principle of the test that based on a stepwise procedure with the use of a minimum number of animals per step, sufficient information is obtained on the acute toxicity of the test substance to enable its classification. The substance is administered orally to a group of experimental animals at one of the defined doses. The substance is tested using a stepwise procedure, each step using three animals of a single sex. Absence or presence of compound-related mortality of the animals dosed at one step will determine the next step, i.e.

− no further testing is needed

− dosing of three additional animals, with the same dose

− dosing of three additional animals at the next higher or the next lower dose level. The method will enable a judgment with respect to classifying the test substance to one of a series of toxicity classes.

Methodology:

Selection of Animal Species

The preferred rodent species is the wistar albino rat, although other rodent species may be used. Healthy young adult animals are commonly used laboratory strains should be employed. Females should be nulliparous and non-pregnant. Each animal, at the commencement of its dosing, should be between 6 to 8 weeks old and the weight (150-200gm) should fall in an interval within±20 % of the mean weight of any previously dosed animals.

Housing and Feeding Conditions

The temperature in the experimental animal room should be 22ºC ± 3ºC. Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning the aim should be 50-60%. Lighting should be artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. Animals may be group-caged by dose, but the number of animals per cage must not interfere with clear observations of each animal.

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Test Animals and Test Conditions:

Sexually mature Female Wistar albino rats (150-200gm) were obtained from TANUVAS, Madhavaram, Chennai. All the animals were kept under standard environmental condition (22±3°C). The animals had free access to water and standard pellet diet (Sai meera foods, Bangalore).

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Preparation for Acute Toxicity Studies

Rats were deprived of food overnight (but not water 16-18 h) prior to administration of the, ***SAARANAI ENNAI***.

The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of the animals and the study design

IAEC approved Number: LV/13/CLBMCP/2018

Test Substance	**:**	**SAARANAI ENNAI**
Animal Source	**:**	TANUVAS, Madhavaram, Chennai.
Animals	**:**	Wister Albino Rats (Female-3+3)
Age	**:**	6-8 weeks
Body Weight on Day 0	**:**	150-200gm.
Acclimatization	**:**	Seven days prior to dosing.
Veterinary examination	**:**	Prior and at the end of the acclimatization period.
Identification of animals	**:**	By cage number, animal number and individual marking by using Picric acid.
Number of animals	**:**	3 Female/group,
Route of administration	**:**	Oral
Diet	**:**	Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore
Water	**:**	Aqua guard portable water in polypropylene bottles.

Housing & Environment	**:**	The animals were housed in Polypropylene cages provided with bedding of husk.
Housing temperature	**:**	between 22ºC + 3ºC.
Relative humidity	**:**	between 30% and 70%,
Air changes	**:**	10 to 15 per hour and
Dark and light cycle	**:**	12**:**12 hours.
Duration of the study	**:**	14 Days

Administration of Doses:

SAARANAI ENNAI was suspended in water and administered to the groups of wistar albino rats in a single oral dose by gavage using a feeding needle. The control group received an equal volume of the vehicle. Animals were fasted 12 hours prior to dosing. Following the period of fasting, the animals were weighed and then the test substance was administered. Three Female animals are used for each group. The dose level of 9mg/kg body weight was administered. After the substance has been administered, food was withheld for a further 3-4 hours. The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously as per the guideline after substance administration. The visual observations included skin changes, mobility, aggressively, sensitivity to sound and pain, as well as respiratory movements. Finally, the number of survivors was noted after 24 hrs and these animals were then monitored for a further 14 days and observations made daily. The toxicological effect was assessed on the basis of mortality.

Observations:

Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours, and daily thereafter, for a total of 14 days, except where they need to be removed from the study and humanely killed for animal welfare reasons or are found dead. It should be determined by the toxic reactions, time of onset and length of recovery period, and may thus be extended when considered necessary. The times at which signs of toxicity appear and disappear are important, especially if there is a tendency for toxic signs to be delayed. All observations are systematically recorded with individual records being maintained for each animal.

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behavior pattern. Attention was directed to observations of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanly killed. When animals are killed for human reasons or found dead, the time of death was recorded.

Acute oral toxicity study of SAARANAI ENNAI

Table 1: Dose finding experiment and its behavioral Signs of acute oral Toxicity

Observation done:

SL	Group CONTROL	Observation	SL	Group TEST GROUP	Observation
1.	Body weight	Normal	1.	Body weight	Normally increased
2.	Assessments of posture	Normal	2.	Assessments of posture	Normal
3.	Signs of Convulsion Limb paralysis	Normal	3.	Signs of Convulsin Limb paralysis	Absence of sign (-)
4.	Body tone	Normal	4.	Body tone	Normal
5.	Lacrimation	Normal	5.	Lacrimation	Absence
6.	Salivation	Normal	6.	Salivation	Absence
7.	Change in skin color	No significant color change	7.	Change in skin color	No significant color change
8.	Piloerection	Normal	8.	Piloerection	Normal
9.	Defecation	Normal	9.	Defecation	Normal
10.	Sensitivity response	Normal	10.	Sensitivity response	Normal
11.	Locomotion	Normal	11.	Locomotion	Normal
12.	Muscle gripness	Normal	12.	Muscle gripness	Normal
13.	Rearing	Mild	13.	Rearing	Mild
14.	Urination	Normal	14.	Urination	Normal

Behaviour:

The animals will be observed closely for behaviour in the first four hours which includes abnormal gait, aggressiveness, exophthalmos, ptosis, akinesia, catalepsy, convolusion, excitation, head twitches, lacrimation, loss of corneal reflex, loss of traction, piloerection reactivity of touch, salivation, scratching, sedation,

chewing, head movements, sniffing, straub, tremor and writhes, diarrhea, leathery, sleep and coma.

Body Weight:

Individual weight of animals was determined before the test substance was administered and weights will be recorded at day 1, 7, and 14 of the study. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and humanly killed.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Mortality:

Animals were observed for mortality throughout the entire period.

Results:

All data were summarized in tabular form, (Table-1-4) showing for each test group the number of animals used, the number of animals displaying signs of toxicity, the number of animals found dead during the test, description of toxic symptoms, weight changes, food and water intake

No of animals in each group:3

Table 2 (Observational study Results)

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	Control	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.	2000mg	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

1..Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhea 18. Writhing ,19. Respiration 20. Mortality.

(+ Present, - Absent)

Table 3 (Body weight Observation)

DOSE	DAYS		
	1	7	14
CONTROL	260.2±12.30	268.4 ± 14.22	274.6 ±16.18
HIGH DOSE	286.4± 2.21	290.64 ± 3.64	296.4 ± 2.18
P value (p)*	NS	NS	NS

Table 3 (Water intake (ml/day) of Wistar albino rats group exposed to *SAARANAI ENNAI:*

DOSE	DAYS		
	1	6	14
CONTROL	61 ± 1.12	64.54±2.22	66.9±3.14
HIGH DOSE	66.2±1.22	69±1.34	72.20±28
P value (p)*	NS	NS	NS

N.S- Not Significant, **($p > 0.01$), *($p > 0.05$), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 4: Food intake (gm/day) of Wistar albino rats group exposed to *SAARANAI ENNAI*

DOSE	**DAYS**		
	1	7	14
CONTROL	68.16±2.34	76.2±4.42	86.4±3.26
High DOSE	84.6±1.42	86.6±2.68	89.1±5.38

REPEATED DOSE 28-DAY ORAL TOXICITY STUDY OF *SAARANAI ENNAI*

Test Substance : **SAARANAI ENNAI**
Animal Source : TANUVAS, Madhavaram, Chennai.
Animals ; Wister Albino Rats (Male -24, and Female-24)
Age : 6-8 weeks
Body Weight : 150-200gm.
Acclimatization : Seven days prior to dose.
Veterinary examination : Prior and at the end of the acclimatization period.
Identification of animals : By cage number, animal number and individual marking by using Picric acid
Diet : Pellet feed supplied by Sai meera foods PvtLtd, Bangalore
Water : Aqua guard portable water in polypropylene bottles.
Housing & Environment : The animals were housed in Polypropylene cages provided with bedding of husk.
Housing temperature : between 22ºC $\pm$ 3ºC.
Relative humidity : between 30% and 70%,
Air changes : 10 to 15 per hour
Dark and light cycle : 12:12 hours.
Duration of the study : **28 Days.**

Table 5

Groups	**No of Rats**
Group I Vehicle control (Water)	12(6male,6 female)
Group II SEI - low dose X (.75ml)	12 (6male,6 female)
Group III SEI- Mid dose 3X (2.25ml)	12 (6male,6female)
Group IV SEI- High dose 6X(4.50ml)	12(6male,6female)

SEI-SAARANAI ENNAI

Methodology

Randomization, Numbering and Grouping of Animals:

48 Wistar Albino Rats (24M + 24F) were selected and divided into 4 groups. Each group consist of 12 animals (Male -6, and Female-6). First group treated as a control and other three group were treated with test drug (low, mid, high) for 28 days. Animals were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal was marked with picric acid. The females were nulliparous and non-pregnant.

Justification for Dose Selection:

As per OECD guideline three dose levels were selected for the study. They are low dose (X), mid dose dose (3X), high dose (6X). X is calculated by multiplying the therapeutic dose (30 ml) and the body surface area of the rat (0.018). i.e X dose is 0.54ml/animal, (rounded to 0.5ml), 3X dose is 1.5ml/animal,6X dose is 3ml/animal.

Preparation and Administration of Dose:

SAARANAI ENNAI suspended in with water, It was administered to animals at the dose levels of X, 3X, 6X. The test substance suspensions were freshly prepared every two days once for 28 days. The control animals were administered vehicle only. The drug was administered orally by using oral gavage once daily for 28 consecutive days.

OBSERVATIONS:

Experimental animals were kept under observation throughout the course of study for the following:

Body Weight:

Weight of each rat was recorded on day 0, at weekly intervals throughout the course of study.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Clinical signs:

All animals were observed daily for clinical signs. The time of onset, intensity and duration of these symptoms, if any, were recorded.

Mortality:

All animals were observed twice daily for mortality during entire course of study.

Necropsy:

All the animals were sacrificed by excessive anaesthesia on day 29. Necropsy of all animals was carried out.

Laboratory Investigations:

Following laboratory investigations were carried out on day 29 in animals fasted over-night. Blood samples were collected from orbital sinus using sodium heparin (200IU/ml) for Bio chemiSEIy and potassium EDTA (1.5 mg/ml) for Hematology as anticoagulant. Blood samples were centrifuged at 3000 r.p.m. for 10 minutes.

Haematological Investigations:

Haematological parameters were determined using Haematology analyzer.

Biochemical Investigations:

Biochemical parameters were determined using auto-analyzer.

Histopathology:

Control and highest dose group animals will be initially subjected to histopathological investigations. If any abnormality found in the highest dose group than the low, then the mid dose group will also be examined. Organs will be collected from all animals and preserved in 10% buffered neutral formalin for 24 h and washed in running water for 24 h. The organ sliced 5 or 6µm sections and were dehydrated in an auto technicon and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" moulds. It was followed by microtome and the slides were stained withHaematoxylin-eosin red.

Statistical analysis:

Findings such as body weight changes, water and food consumption, hematology and blood chemiSEIy were subjected to One-way ANOVA followed by dunnet t test using a computer software programme – Graph pad version 7. All data were summarized in tabular form, (Table-6 to 12).

RESULTS

Repeated Dose 28- day oral toxic study ofSAARANAI ENNAI

Table 6: Body weight of wistar albino rats group exposed to *SAARANAI ENNAI*

DOSE	DAYS				
	1	7	14	21	28
CONTROL	220.6±33.673	221.4 ± 40.114	221.7 ± 39.661	222.6 ± 39.73	222.7 ± 41.311
LOW DOSE	180.2 ± 21.124	180.7 ± 33.64	181.4± 21.514	182 ± 21.66	182.42± 12.76
MID DOSE	176.6± 10.64	176.3 ± 22.74	176.4 ± 38.12	178.1 ± 33.36	179.7 ± 23.12
HIGH DOSE	187.4± 36.74	187.6 ± 32.72	187.6 ± 32.46	187 ± 22.78	186.92 ± 26.49
P value (p)*	NS	NS	NS	NS	NS

NS- Not Significant, **(p > 0.01),*(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 7: Water intake (ml/day) of Wistar albino rats group exposed to *SAARANAI ENNAI*

DOSE	DAYS				
	1	6	14	21	28
CONTROL	61.5 ± 8.95	61±6.23	58.5±6.23	59±8.196	61.5±3.96
LOW DOSE	56.5±3.31	56.4±3.62	56.7±3.26	56.2±3.29	56.9±3.13
MID DOSE	55.7±4.33	56.3±2.11	57.1±2.43	58.4±2.11	58.4±2.34
HIGH DOSE	60.1±1.32	60.2±2.13	60.7±2.13	65.2±1.73	63.4±2.65
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 8: Food intake (gm/day) of Wistar albino rats group exposed to *SAARANAI ENNAI*

DOSE	DAYS				
	2	7	23	22	28
CONTROL	37±5.37	38.5±3.22	39.5±3.37	38.5±3.37	37±3.12
LOW DOSE	43.7±2.98	45.3±1.22	45.1±1.18	45.4±2.12	45.6±2.42
MID DOSE	47.2±3.75	47.2±3.60	47.2±4.25	47.4±2.68	49.2±2.44
HIGH DOSE	46.2±2.34	46.2±2.64	49.6±2.66	48.2±3.20	48.0±3.62
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

Table 9: Haematological parameters of Wistar albino rats group exposed to *SAARANAI ENNAI*

Category	Control	Low dose	Mid dose	High dose	P value (p)*
Haemoglobin (g/dl	13.8±0.88	13.80±0.66	14.14±0.66	13.28±0.96	N.S
Total WBC (×10^3 l)	11.91±0.59	11.25±0.73	11.48±0.91	11.20±1.17	N.S
Neutrophils (%)	33.65±0.06	32.23±0.14	35.41±1.36	35.20±2.20	N.S
lymphocyte (%)	70.24±1.48	70.12±3.12	70.20±2.66	70.10±2.16	N.S
Monocyte (%)	0.86±0.07	0.84±0.09	0.82±0.03	0.81±0.06	N.S
Eosinohil(%)	0.54±0.09	0.56±0.02	0.56±0.06	0.57±0.04	N.S
Platelets cells10^3/µl	687.17±8.76	688.71±8.16	683.18±9.0	687.16±9.74	N.S
Total RBC 10^6/µl	7.99±0.12	7.99±0.57	7.82±0.59	8.05±0.72	N.S
PCV%	37.79±0.6	41.35±1.13	43±1.68	45.82±2.54	N.S
MCHC g/Dl	33.6±2.23	35.09±1.29	36.98±1.22	34.03±1.24	N.S
MCV fL(µm^3)	49.07±3.64	50.20±1.22	51.20±1.24	52.24±1.44	N.S

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 10 :Biochemical Parameters of of Wistar albino rats group exposed to *SAARANAI ENNAI*

BIOCHEMICAL PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
GLUCOSE (R) (mg/dl)	74.45±13.4	76.16±8.44	78.26±11.20	76.42±11.6	N.S
T.CHOLOSTEROL (mg/dl)	115.26±1.83	115.45±1.83	116.42±1.78	116.22±1.73	N.S
TRIGLY(mg/dl)	46.35±1.48	46.32±1.48	44.58±1.30	45.66±1.33*	N.S
LDL	73.8±2.43	73.24±2.54	73±2.44	73.64±24.32	NS
VLDL	15.2±2.44	15.42±4.64	15.44±6.64	15.64±34.36	NS
HDL	26.66±6.88	26.86±2.24	26.68±4.66	26.78±21.22	NS
Ratio 1 (T.CHO/HDL)	4.42±2.44	4.46±3.14	4.44±8.44	4.46±22.22	NS
Ratio 2 (LDL/HDL)	2.83±24.22	2.84±2.22	2.86±2.20	2.66±46.02	NS
Albumin (g/dL)	3.3±0.17	3.43±0.12	3.34±22.02	3.54±6.86	NS

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 11: Renal function test of of Wistar albino rats group exposed to *SAARANAI ENNAI*

PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
UREA (mg/dl)	13.35±0.99	14.31±0.46	14.06±1.38	14.48±1.42	N.S
CREATININE (mg/dl)	0.58±0.08	0.46±0.06	0.62±0.04	0.66±0.02	N.S
BUN(mg/dL)	15.12±0.10	15.10±0.60	16±0.44	16.10±2.12	NS
URIC ACID(mg/dl)	5.37±0.35	5.11±0.43	5.7±1.25*	5.48±0.23	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05) , n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 12: Liver Function Test of of Wistar albino rats group exposed to *SAARANAI ENNAI*

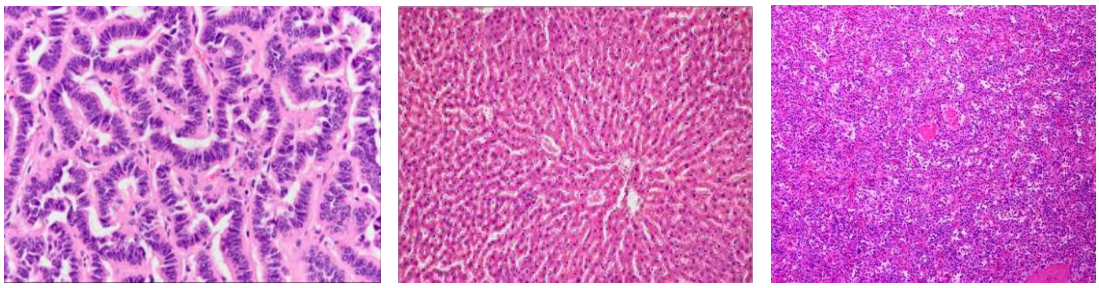
PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
T BILIRUBIN (mg/dl).	0.50±0.07	0.55±0.06	0.59±0.08	0.56±0.05	N.S
SGOT/AST(U/L)	114.95±1.39	116.35±0.51	117.01±1.53	116.55±1.03	N.S
SGPT/ALT(U/L)	71.23±1.28	75.91±1.59	75.34±1.48	74.32±0.68	N.S
ALP(U/L)	146.25±8.77	141±16.17	148.16±24.07*	149.33±14.65*	N.S
T.PROTEIN(g/dL)	6.32±0.38	7.48±0.34	7.016±0.23	6.53±0.46	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

HISTO PATHOLOGY

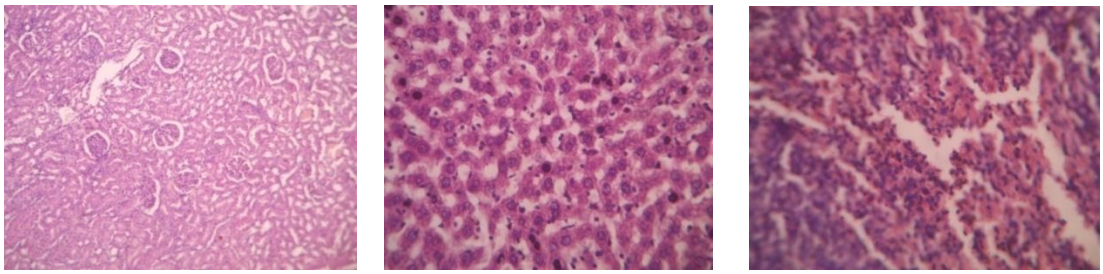
CONTROL GROUP

Kidney Liver Spleen



TEST GROUP(HIGH DOSE)

Kidney Liver Spleen



PHARMACOLOGICAL ACTIVITY

ANTI HISTAMINE ACTIVITY

Materials and methods

Pharmacological Study: guinea-pig ileum. Terminal segments of ileum, about 3 cm in length, were prepared from fasted (48 h) male guinea pigs (400-800 g) provided by the animal house of C.L.Baid Metha college of Pharmacy, Chennai.

These cut segments were placed in 25 mL baths with Tyrode solution (NaCI 137, KCI 2.68, $MgSO_4.7H_201$ .05, NaH_2 $P0_4.H_20$ 0.34, glucose 5.55, $CaCl_2$ 1.78, $NaHCO_3$, 11 mM). The solution was kept at 37°C and gassed with 5% CO_2 in O_2. Initial tension was 1gm and the stabilization time was 30-45 min. Isometric contractions were recorded on a Panlab transducer connected to a Panlab Omniscribe recorder.

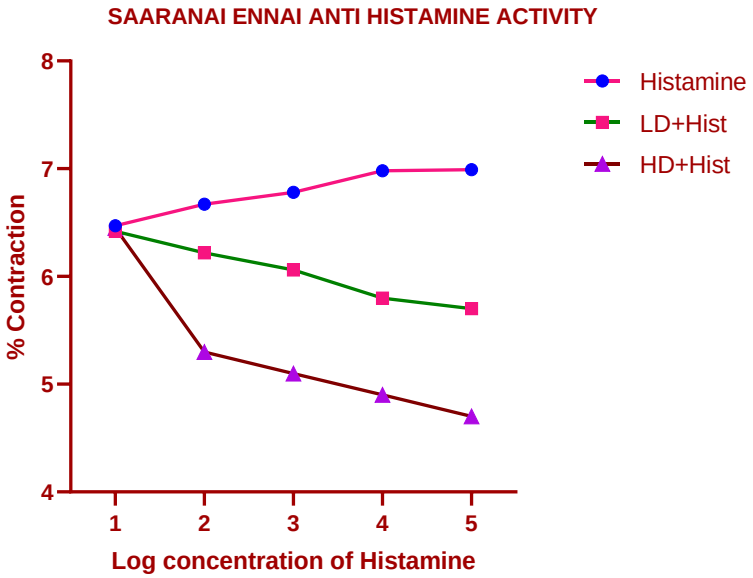
Increasing concentrations of histamine were added to the bath at 30 min intervals and a control cumulative concentration response curve was recorded. chlorpheniramine was then added to the bath 5 min before the corresponding concentration response curve was recorded.

The antihistamine effects of clorpheniramine were evaluated against a fixed, minimally effective dose of histamine (6.7×10^{-8} M), in terms of their ability to prevent the histamine contractions when they were added to the bath 5 min before the histamine.

Animal used: Guinea pig

Substances and drugs used:

These were Dexchlorpheniramine maleate (Schering Corporation), Saaranai Ennai , Histamine hydrochloride (Sigma Aldrich)



Since the contraction of Histamine in the guinea pig ileum has reduced in the presence of Saaranai Ennai, low dose and high dose of the drug shows Anti histamine activity.

MATERIALS AND METHODS

STUDY DESIGN

An open clinical trial on *Bala karappan* was carried out in the post graduate department of *Kuzhanthai Maruthuvam* in Govt siddha medical college attached to Arignar Anna Govt Hospital of Indian medicine, Chennai -106 during the period of 2017-2019.

The study was approved on **Institutional ethics committee (IEC) and** the approval number is **GSMC-CH-ME- 2/020/2017.**

STUDY SIZE

The study was conducted in 40 selected patients of both genders of between age groups of 6 to12 years.

SELECTION CRITERIA

The patients having any 4 of the following parameters are selected for the study

- Age:6 to 12 years
- Itching
- Erythema
- Weeping
- Vesicles
- Oozing
- Lichenification

EXCLUSION CRITERIA

- Scabies
- Photodermatitis
- Secondary bacterial infection

WITHDRAWAL CRITERIA:

- Exacerbations of symptoms
- Intolerance to the drug and development of adverse reactions during the trial drug .
- Patients turned unwilling to continue in the course of clinical trial.
- Any other acute illness

TESTS AND ASSESSMENTS:

A. Clinical Assessment
B. Siddha Assessment
C. Laboratory Investigations

Clinical Assessment:

- Itching
- Papules
- Vesicles
- Scaling
- Oozing
- Hyperpigmentation

Siddha Assessment:

- Naa
- Niram
- Mozhi
- Vizhi
- Sparisam
- Malam
- Naadi
- Moothiram-neer kuri,nei kuri.

Laboratory Investigations

Blood : TC, DC, ESR, HB

Urine : Albumin, Sugar, Deposit

Special investigation:

EASI (Eczema Area Severity Index) Score Assesment

METHODOLOGY OF TREATMENT

Study enrolment:

Patient's parent or guardian reporting at the OPD with child associated with clinical features of severe itching, erythema, vesicles, papules, oozing and lichenification are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study of trial drug *Saaranai ennai (Internal & External),* possible outcomes and the objectives of the study in their own language and terms understandable to them and the informed consentwould be obtained from the patient's parent or guardian using consent form.

Conduct of the study

On the first day onwards the trial drug "*Saaranai ennai (Internal & External)"* will be given. The trial drug will be given in the OPD department of *kuzhanthai Maruthuvam,* GSMC, Chennai. The patients will be asked to have a regular follow up in the OP department once in 5 days. In each and every visit the clinical assessment will be recorded in the prescribed proforma. The laboratory investigationwill be done before and after treatment and recorded in the prescribed format.

Data collection forms

Required information will be collected from each patient by using following foms:

Form I : Screening and selection proforma
Form II : History taking proforma
Form III : Clinical assessment proforma
Form IV : Laboratory investigation proforma
FormV : Informed consent form
Form VI : Withdrawal form
FormnVII : Patient information sheet
Form VIII : Informed Assent form
Form IX : Diet sheet

Data Analysis:

After enrolling the patients in the study a separate file for each patient is maintained and all forms are kept in the file. Whenever the patient visits OPD during

the study period necessary entries will be made in the assessment forms. The data entries and adverse events if any will be monitored by the Head of the Department.

OUTCOME OF TREATMENT

Primary Outcome

Primary outcome is mainly assessed by reduction in clinical symptoms

Secondary Outcome

Safety of the patients is assessed as a secondary outcome through LFT/ RFT

Adverse effect and serious effect management

If the trial patient develops any adverse reactions the patient will be referred to the pharmacovigilence department of SCRI and documented. For any adverse effect the investigator will give the proper management in the OPD.

Ethical issues

1. Informed Consent/Assent will be obtained from the patient/ patient's parent or guardian after explaining about the clinical trial in their language.
2. After the Consent/Assent of te patient or patients parent (through consent/Assent form) if they fit in the criteria they will be enrolled in the study.
3. Treatment will be provided free of cost.
4. Concomitant medicines will be used if there is any need.
5. The patients who are excluded (as per the exclusion criteria) will be referred to OPD
6. In conditions of treatment failure, adverse reaction patients will be given rescue medication.

Analysis of Trial medicine:

1. Dermal toxicity study was carried out in CL Baid Metha College of Pharmacy, Thorraipakkam, Chennai.
2. The pharmacological activity of trial drug for the Antihistamine activity was carried out in CL Baid Metha College of Pharmacy, Thorraipakkam, Chennai.
3. Physiochremical and phytochemical analysis wasperformed in CL Baid Metha College of Pharmacy, Thorraipakkam, Chennai.
4. Observation made form patients with sign and symptoms of the disease and their prognosis were recorded.

RESULTS AND OBSERVATION

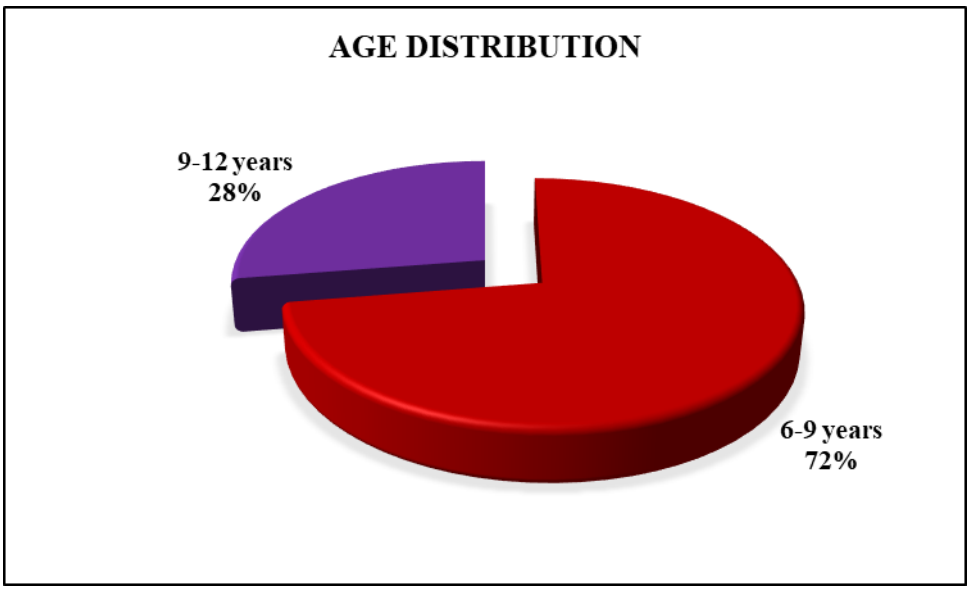
A total number of 40 child patients with signs and symptoms of ***Bala karappan*** attending PG-IV, *Kuzhanthai Maruthuvam* Out Patient Department in Govt. Siddha Medical College attached to Aringnar Anna Hospital were observed in the present study. The observations were made and tabulated with regards to the following features:

1. **Age Distribution**
2. **Gender Distribution**
3. **Socio-Economic status**
4. **Aetiological factor**
5. **Dietary habits**
6. **Seasonal reference**
7. **Reference to Thinai**
8. **UyirThathukkal**
9. **Udarthathukkal**
10. **Envagaithervugal**
11. **Neikkuri**
12. **Clinical prognosis**
13. **Results after treatment**

The observation recorded are given below in tabular form

1. AGE DISTRIBUTION

S.NO.	AGE	NO. OF CASES	PERCENTAGE
1	6 – 9 yrs	29	72.5%
2	9 - 12yrs	11	27.5%

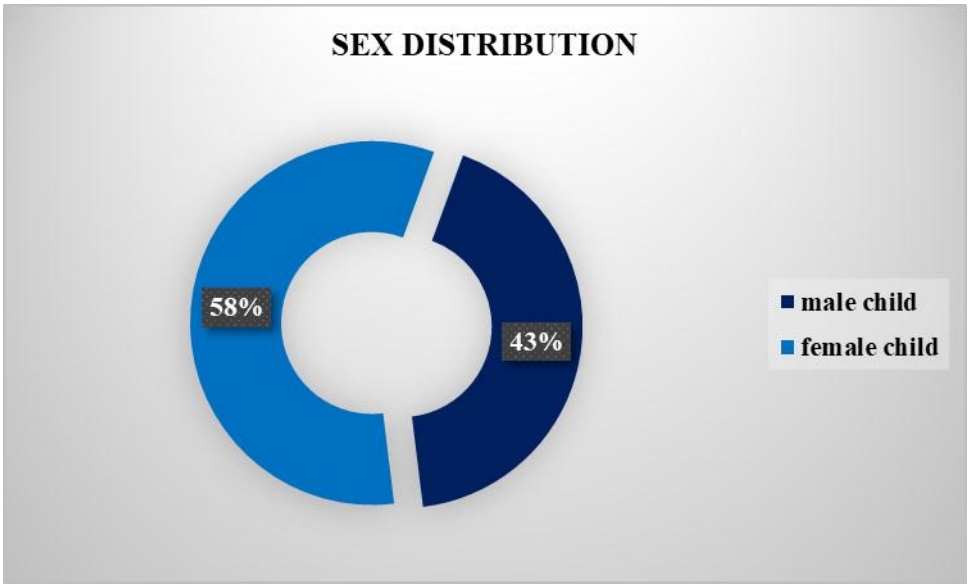


Inference

The above table indicates that children coming under 6-9 years of age group were 29(72.5%), 9-12 years were 11(27.5%) respectively.

2. SEX DISTRIBUTION

S.NO.	SEX	NO. OF CASES	PERCENTAGE
1	Male child	17	42.5%
2	Female child	23	57.5%

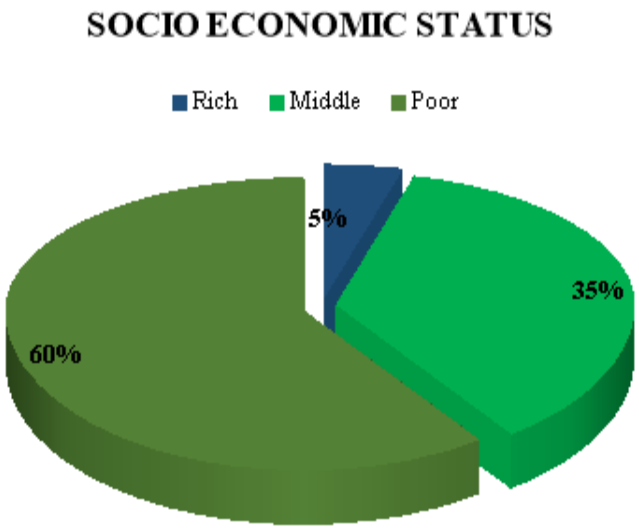


Inference

Among the 40 cases for this present study, 17(42.5%) children were male and 23(57.5%) children were female. According to modern theory there is no apparent sex prediction.

3. SOCIO ECONOMIC STATUS

S.NO.	STATUS	NO. OF CASES	PERCENTAGE
1	Rich	2	5%
2	Middle	14	35%
3	Poor	24	60%

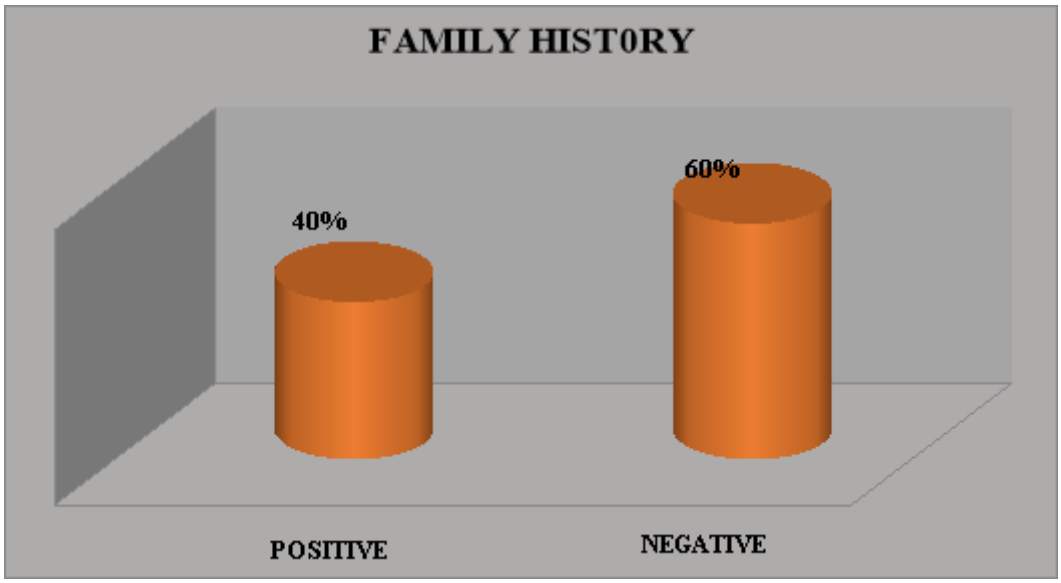


Inference

Regarding socio-economic status, 24(60%) cases were belong to poor status, 14(35%) cases were belong to middle class and 2(5%) cases belong to high class.

4. FAMILY HISTORY

S.No	Family History	No. Of Cases	Percentage
1.	Positive	16	40%
2.	Negative	24	60%

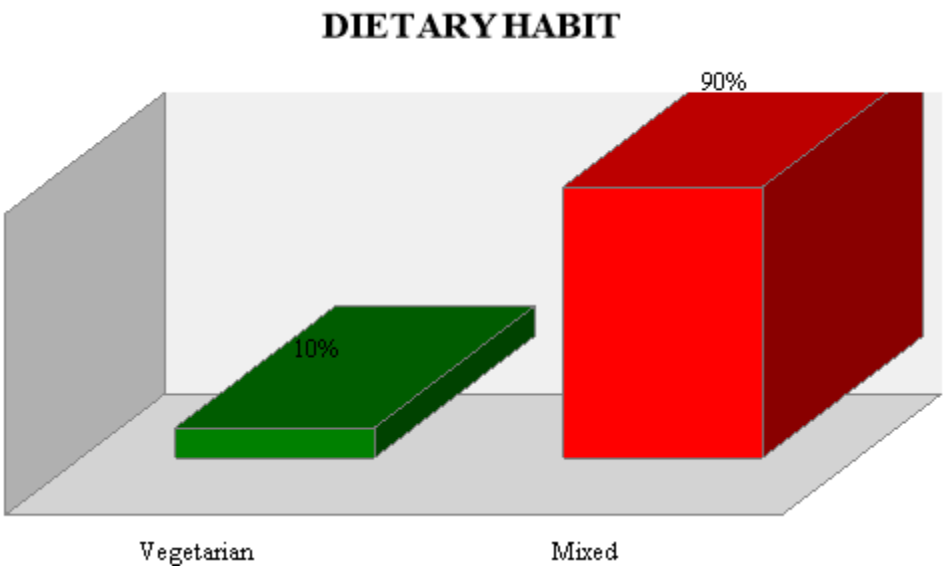


Inference:

Among the 40 patients, 24(60%) of the patients showed negative family history, 16(40%) patients showed positive family history.

5. DIETARY HABITS:

S. No	Diet	No. of cases	Percentage
1.	Vegetarian	4	10%
2	Mixed	36	90%

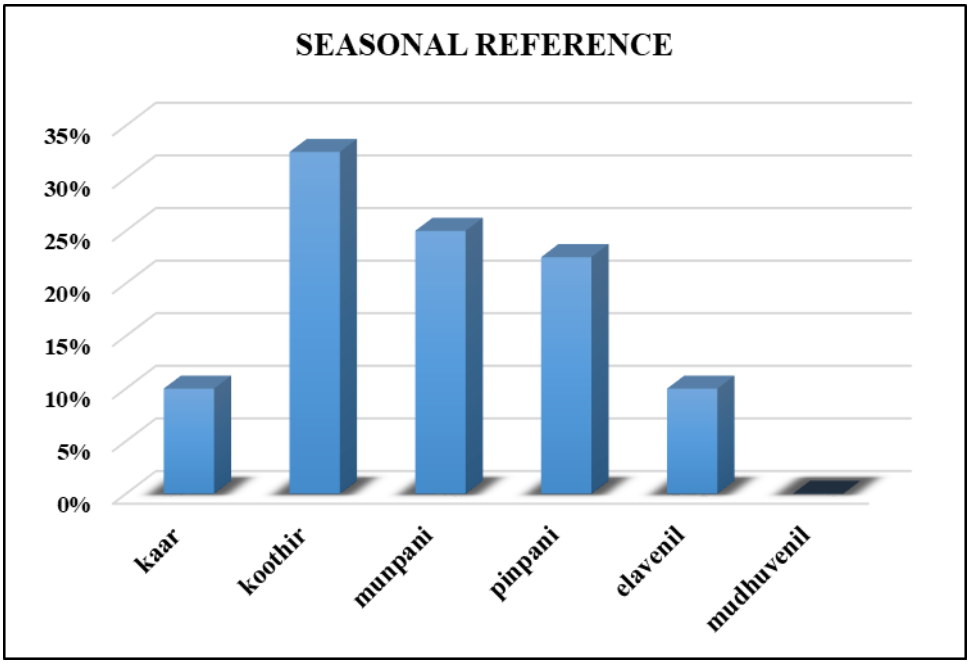


Inference:

90% belonged to mixed diet and 10% belonged to vegetarian diet habit.

6. SEASONAL REFERENCE

S.NO.	KAALANGAL	NO.OF CASES	PERCENTAGE
1	Kaar(Aavani, purattasi)	4	10%
2	Koothir (Iypasi, karthigai)	13	32.5%
3	Munpani (Margazhi, Thai)	10	25%
4	Pinpani (Masi, Pankuni)	9	22.5%
5	Elavenil (Chithirai, Vaikasi)	4	10%
6	Muduvenil (Aani, Aadi)	0	0%

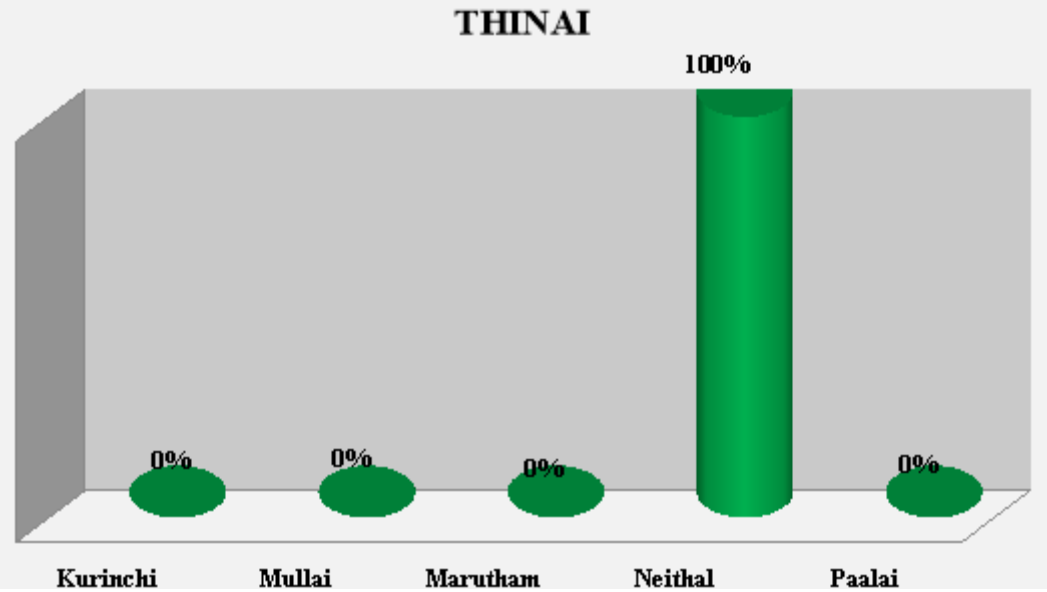


Inference :

Regarding *Paruvakaalam* among 40 cases, 4(10%) cases were reported in Kaarkaalam, 13(32.5%) cases were reported in *Koothirkaalam*, 10(25%) cases were reported in *Munpanikaalam*, 9(22.5%) cases were reported in *Pinpanikaalam*, 4(10%) cases were reported in *ElavenilKaalam*.

7. REFERENCE TO THINAI:

S.NO.	NILAM	NO. OF CASES	PERCENTAGE
1	Kurinchi	0	0%
2	Mullai	0	0%
3	Marutham	0	0%`
4	Neithal	40	100%
5	Paalai	0	0%



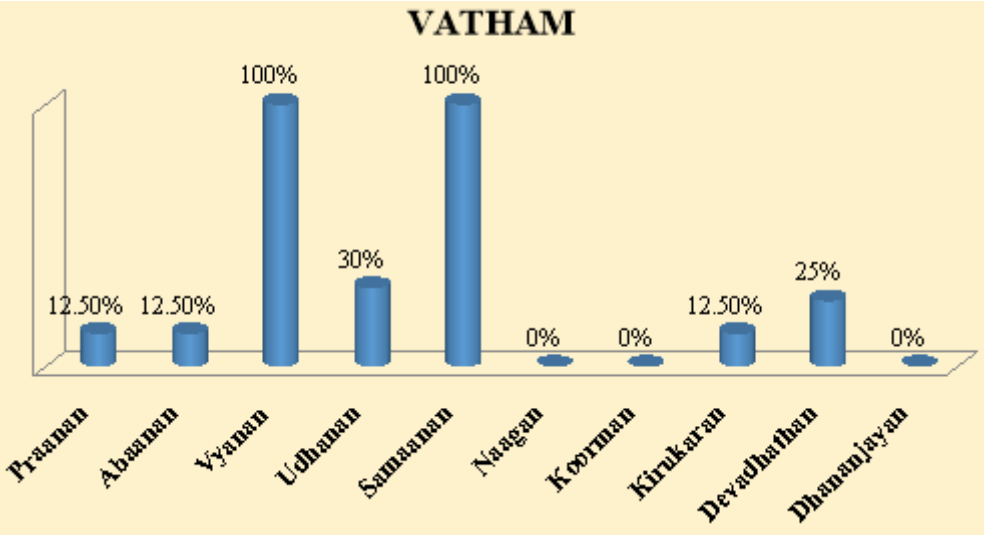
Inference

All the 40 cases,were reported from surroundings of Chennai which belongs to *Neithalnilam.* This is due to the fact that the study was conducted at Chennai a Neithal land and so majority of the cases were from that land.

8. UYIR THATHUKKA

a)AFFECTED VATHAM:

S.No.	Vatham	No. of cases	Percentage
1	*Praanan*	5	12.5%
2	*Abaanan*	5	12.5%
3	*Vyanan*	40	100%
4	*Udhanan*	12	30%
5	*Samaanan*	40	100%
6	*Naagan*	0	0%
7	*Koorman*	0	0%
8	*Kirukaran*	5	12.5%
9	*Devadhathan*	10	25%
10	*Dhananjayan*	0	0%

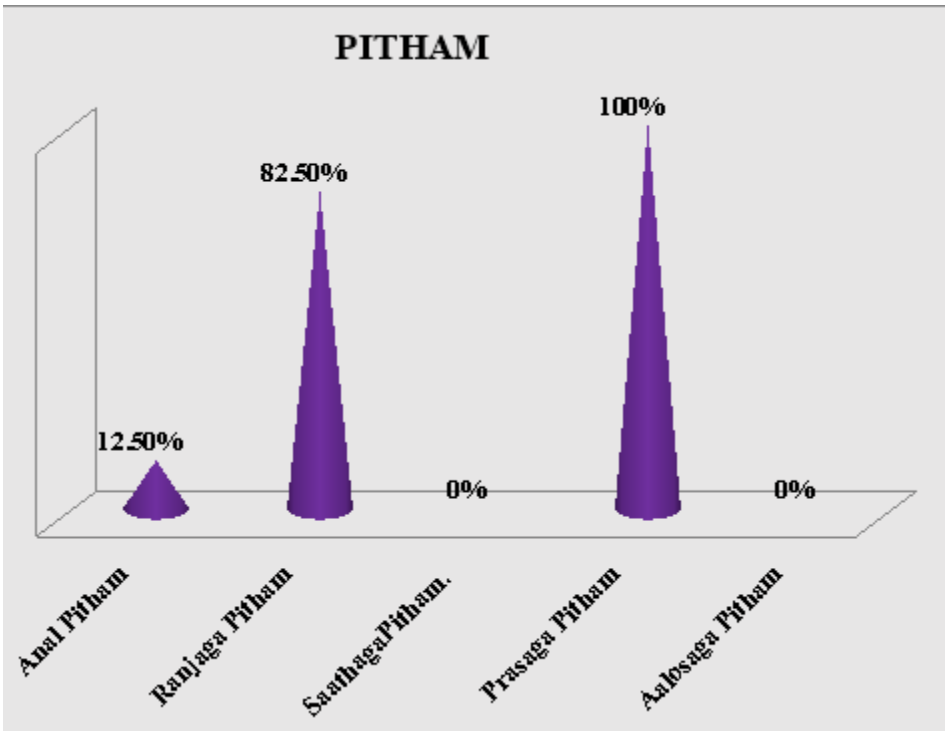


Inference:

In 40 cases, among 10 types of *Vaatham, Praanan* were affected in 5 (12.5%) cases, *Abaanan* were affected in 5 (12.5%)cases,vyanan were affected in 40(100%) cases, *Udhanan* were affected in 12(30%) cases, *samaanan* were affected in 40(100%) cases, *kirukaran* were affected in 5 (12.5%)cases, *Devadhathan* were affected in 10 (25%) cases repectively .

b) AFFECTED PITHAM

S. NO.	PITHAM	NO. OF CASES	PERCENTAGE
1	Anal Pitham	5	12.5%
2	Ranjaga Pitham	33	82.5%
3	Saathaga Pitham	0	0%
4	Prasaga Pitham	40	100%
5	Aalosaga Pitham	0	0%

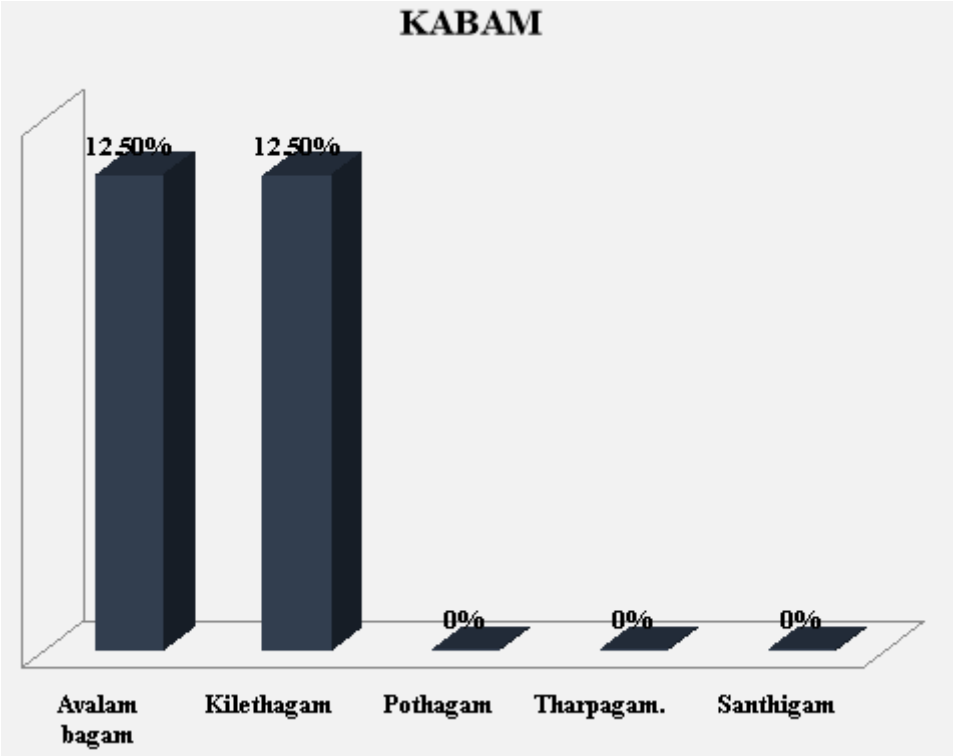


INFERENCE:

Among 5 types *of Pitham*, *Anal pitham* were affected in 5(12.5%) cases, *Ranjaga pitham* were affected in 33 (82.5%) cases, *Prasaga pitham* were affected in 40 (100%) cases respectively.

c) AFFECTED KABAM

S.NO.	KABAM	NO. OF CASES	PERCENTAGE
1	*Avalam bagam*	5	12.5%
2	*Kilethagam*	5	12.5%
3	*Pothagam*	0	0%
4	*Tharpagam.*	0	0%
5	*Santhigam*	0	0%

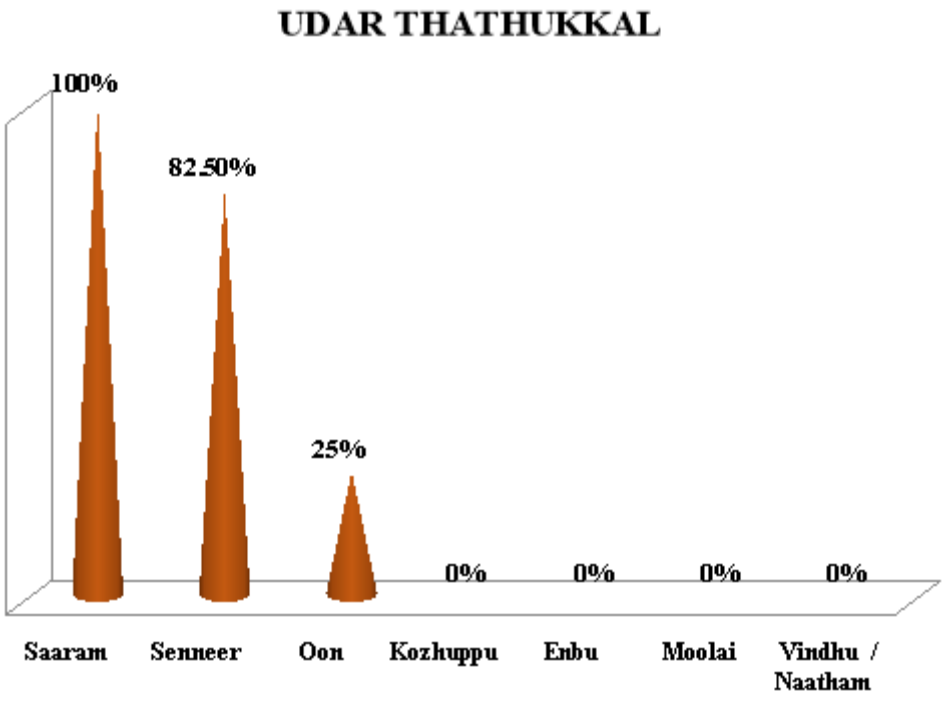


INFERENCE:

Among 40 cases, *Avalambagam and Kilethagam were* affected in 5 (12.5%) cases respectively.

9. UDARTHATHUKKAL

S.NO.	*NAME*	NO. OF CASES	PERCENTAGE
1	*Saaram*	40	100%
2	*Senneer*	33	82.5%
3	*Oon*	10	25%
4	*Kozhuppu*	0	0%
5	*Enbu*	0	0%
6	*Moolai*	0	0%
7	*Vindhu / Naatham*	0	0%

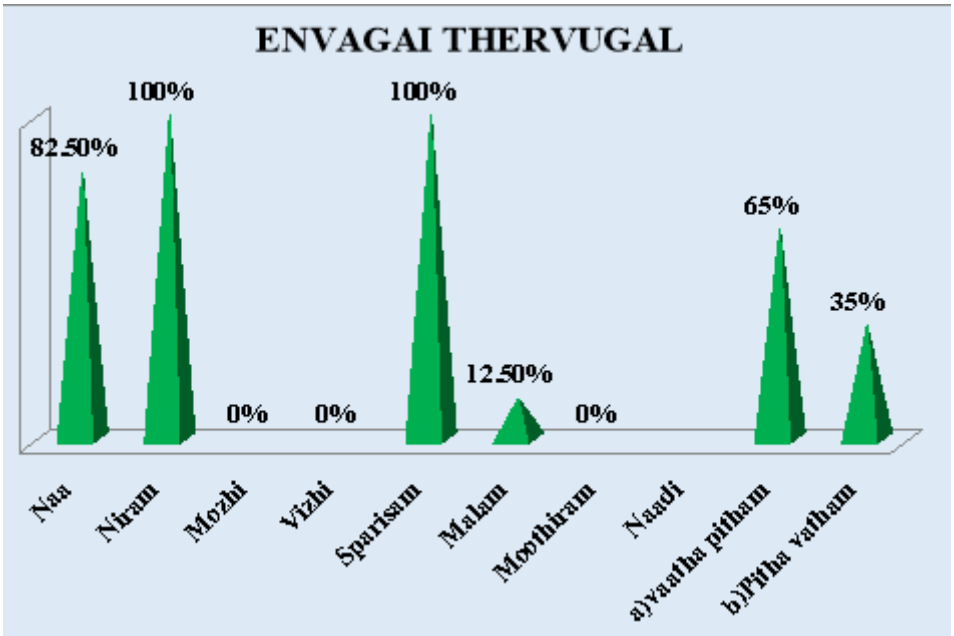


INFERENCE:

In *Udalthathukkal, Saaram* were affected in *40(100%)* cases and *Senneer* were affected in 33(82.5%) cases and *Oon* were affected in 10(25%) cases.

10. ENVAGAI THERVUGAL

S.NO.	SIDDHA PARAMETERS	NO. OF CASES	PERCENTAGE
1	*Naa*	33	82.5%
2	*Niram*	40	100%
3	*Mozhi*	0	0%
4	*Vizhi*	0	0%
5	*Sparisam*	40	100%
6	*Malam*	5	12.5%
7	*Moothiram*	0	0%
8	*Naadi*		
	a)vaatha pitham	26	65%
	b)Pitha vatham	14	35%

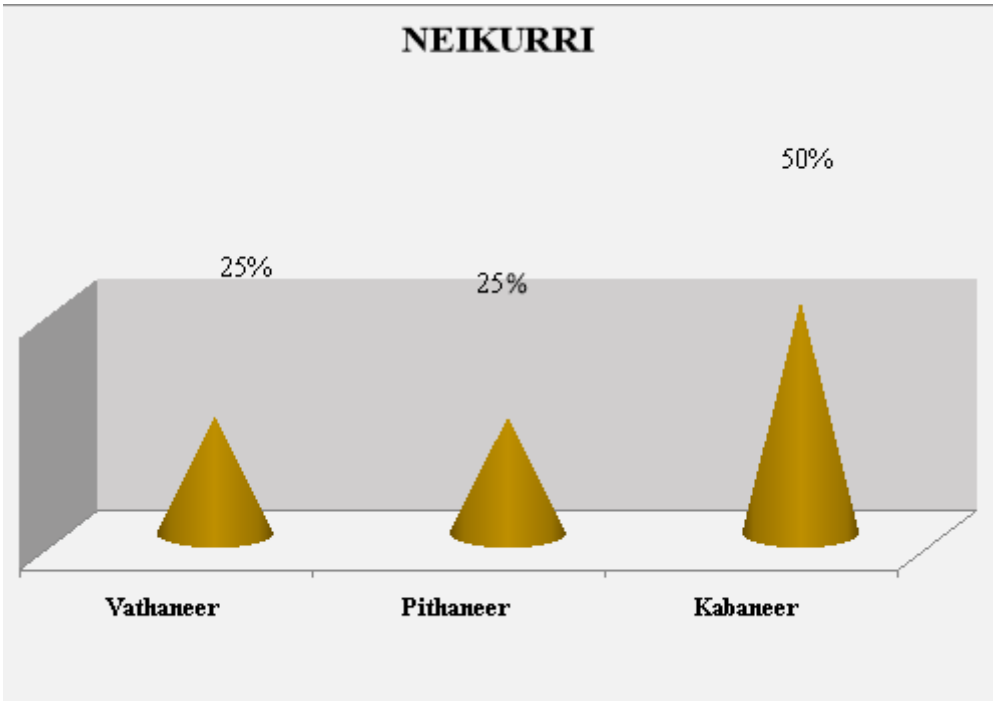


INFERENCE:

Among the Ennvagaithervukal, *Naa* were affected in 33(82.5%) cases, *Niram and Sparisam* were affected in all 40(100%) cases, *Malam* were affected in 5 cases (12.5%) and in *Naadi* 26 (65%) cases were *vaatha pitham and* 14 (35%) cases were *Pitha vatham.*

11. NEIKKURI

S.NO.	TYPE OF NEER	CHARACTER	NO. OF CASES & PERCENTAGE
1	*Vathaneer*	*Aravenaneendal*	10(25%)
2	*Pithaneer*	*Aazhipolparavuthal*	10(25%)
3	*Kabaneer*	*Muththothunitral*	20(50%)

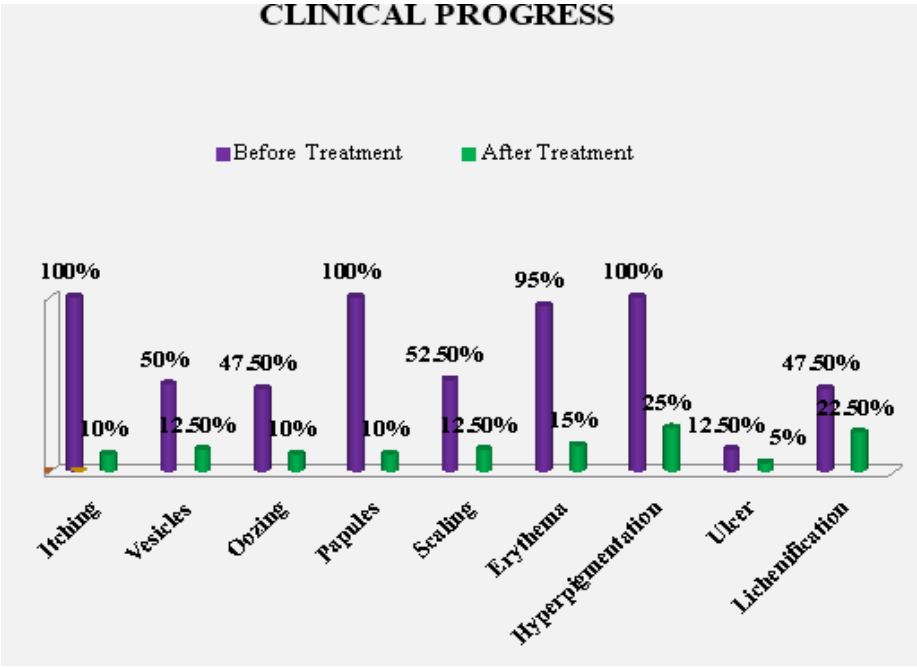


INFERENCE

Among 40 cases, *Vathaneer*was observed in 10(25%) cases, *Pithaneer* was observed in 10(25%) cases, *Kabaneer* was observed in 20(50%) cases.

12. REFERENCE TO CLINICAL FEATURES

S. No.	Clinical features	Before Treatment		After Treatment	
		No.of cases	Percentage	No.of cases	Percentage
1	Itching	40	100%	4	10%
2	Vesicles	20	50%	5	12.5%
3	Oozing	19	47.5%	4	10%
4.	Papules	40	100%	4	10%
5	Scaling	21	52.5%	5	12.5%
6	Erythema	38	95%	6	15%
7	Hyperpigmentation	40	100%	10	25%
8	Ulcer	5	12.5%	2	5%
9	Lichenification	19	47.5%	9	22.5%



Inference

The above table reveals that, among all the 40 cases, Itching was reduced in 36 cases among 40, vesicles was reduced in 15 cases among 20, Oozing was reduced in 15 cases among 19, Papules was reduced in 36 cases among 40, scaling was reduced in 16 cases among 21, Erythema was reduced in 32 cases among 38, Hyperpigmentation was reduced in 30 cases among 40, Ulcer was reduced in 3 cases among 5, Lichenification was reduced in 10 cases among 19 .

CASE SUMMARY OF THE PATIENTS

S.NO	OP.NO	NAME	AGE/SEX	REMARKS
1.	5985	Ganesh	08/MC	Good
2.	3198	Mahath	08/MC	Good
3.	7000	Manju	08/FC	Mild
4.	5984	Kaviya	07/FC	Good
5.	5192	Logeshwaran	09/MC	Moderate
6.	0787	Nithya	07/FC	Good
7.	1474	Preetha	08/FC	Moderate
8.	5846	Dhanuskha	08/FC	Moderate
9.	4868	Manikandan	11/MC	Good
10.	3197	Asvini	07/FC	Good
11.	0775	Gathsoph	09/MC	Good
12.	8013	Labisha	06/FC	Good
13.	5847	Sai dharshini	10/FC	Good
14.	7750	Muhammed khan	$6^{1/2}$/MC	Good
15.	5106	Dhivya	12/FC	Moderate
16.	9421	Nithya	09/FC	Moderate
17.	4740	Yugashni	10/FC	Moderate
18.	6135	Prathiksha	12/FC	Mild
19.	3214	Dharshini	08/FC	Mild
20.	8687	Alkalf	06/MC	Good
21.	8918	Sahitha	$6^{1/2}$/FC	Mild
22.	6197	Sai ganesh	06/MC	Moderate
23.	8674	Dhinesh	12/MC	Good
24.	6999	Sri nisha	07/FC	Mild
25.	0711	Dharshini priya	08/FC	Good
26.	8045	Vigneshwaran	$8^{1/2}$/MC	Good
27.	6994	Kajan karthick	06/MC	Good
28.	8014	Ayeesh	08/MC	Moderate
29.	9337	Akshaya	10/FC	Moderate
30.	5749	Dhivya lakshmi	11/FC	Moderate
31.	1896	Sudha	08/FC	Good
32.	3025	Ila mukilan	06/MC	Good
33.	4705	Samritha	12/FC	Good
34.	8963	Yogesh	10/MC	Good
35.	2040	Madhankumar	11/MC	Good
36.	1678	Kaviya sri	08/FC	Good
37.	9062	Dhinakaran	08/MC	Good
38.	9338	Dharnika	06/FC	Good
39.	7301	Prasanth	06/MC	Good
40.	9420	Nandhini	09/FC	Good

PATIENTS PHOTOS

1. Op No. 9421 (9yrs/fc)

Before treatment

After treatment

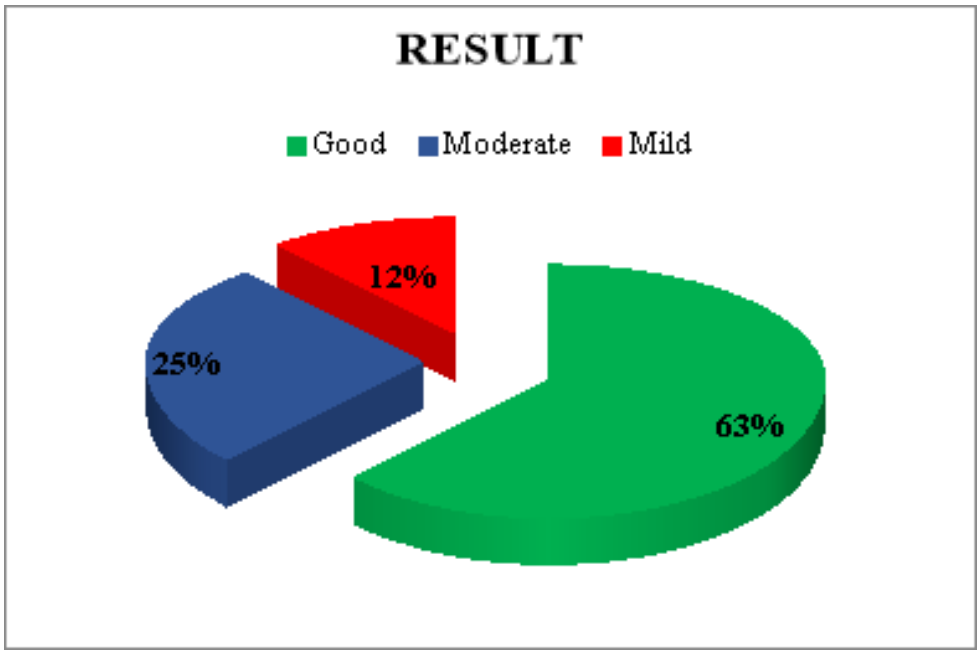
2. Op No. 9062 (8yrs/mc)

Before treatment

After treatment

RESULTS

S.NO	RESULTS	NO: OF CASES	PERCENTAGE
1.	Good	25	62.5 %
2.	Moderate	10	25 %
3.	Mild	5	12.5%



Inference

Among 40 patients 25 (62.5%) cases showed good improvement, 10 (25%) cases showed moderate improvement, 5 (12.5%) cases showed mild improvement.

LABORATORY INVESTIGATION REPORT OF THE PATIENTS

S.NO	NAME	OP. NO	AGE/ SEX	HEMATOLOGICAL ANALYSIS												Hb (gms%)		URINE ANALYSIS					
				BEFORE TREAATMENT						AFTER TREATMENT								BT				AT	
				TC	DC			ESR mm		TC	DC			ESR mm		BT	AT						
					P %	L%	E%	½ hr	1 hr		P%	L%	E%	½ hr	1 hr			Alb	Sug	Dep	Alb	Sug	dep
1.	DHINAKARAN	9062	08/MC	9200	60	35	5	7	18	9000	65	30	3	5	10	11.5	10.8	N	N	N	N	N	N
2.	NITHYA	9421	09/FC	4400	61	30	9	5	12	6900	60	28	5	4	8	10.3	11.5	N	N	N	N	N	N
3.	NANDINI	9420	09/FC	8100	53	38	9	4	8	7200	59	32	3	4	05	11.5	10.9	N	N	N	N	N	N
4.	SABITHA	8918	$6^{1/2}$/FC	10900	41	51	8	4	12	11000	50	45	1	4	10	11.1	11.5	N	N	N	N	N	N
5.	SAI GANESH	6197	06/MC	7700	53	39	8	9	15	8700	59	29	1	5	10	09.2	10.5	N	N	N	N	N	N
6.	MAHATH	3198	08/MC	12100	79	17	6	3	8	11000	65	30	4	3	8	12.0	11.5	N	N	N	N	N	N
7.	PRATHIKSHA	6135	12/FC	7300	48	45	7	3	10	8100	50	40	5	5	9	12.9	12.5	N	N	N	N	N	N
8.	DINESH	8674	12/MC	8400	50	45	5	28	42	8900	55	42	3	10	15	11.7	11.9	N	N	N	N	N	N
9.	NITHYA	0787	07/FC	6000	56	39	5	8	15	7200	52	42	2	4	8	10.4	11.2	N	N	N	N	N	N
10.	YOGESHWARAN	5192	09/MC	7700	55	39	6	23	40	8900	65	40	3	15	25	11.6	12.0	N	N	N	N	N	N
11.	DHARSHINI	3214	08/FC	11300	29	63	8	10	26	10000	50	40	7	9	24	09.9	11.0	N	N	N	N	N	N
12.	KAVIYA SRI	1678	08/FC	10000	77	28	5	12	25	9600	70	28	3	4	12	07.1	10.2	N	N	N	N	N	N
13.	YUGASHINI	4740	10/FC	10500	58	35	7	14	25	9900	50	30	5	5	20	12.1	12.5	N	N	N	N	N	N
14.	GANESH	5985	08/MC	8900	54	40	6	25	42	8800	50	48	3	5	10	13.1	12.2	N	N	N	N	N	N
15.	DHANUSKA	5846	08/FC	7500	66	28	6	4	10	8000	68	30	5	3	9	12.4	11.5	N	N	N	N	N	N
16.	PREETHA	1474	08/FC	8600	77	17	6	8	20	9000	79	20	4	5	15	12.9	12.0	N	N	N	N	N	N
17.	MANJU	7000	08/FC	10600	58	36	6	2	6	11200	60	30	7	2	8	08.6	10.2	N	N	N	N	N	N
18.	KAVIYA	5984	07/FC	10800	58	30	8	2	8	10900	50	48	2	3	5	08.8	10.8	N	N	N	N	N	N
19.	MANIKANDAN	4868	11/MC	6300	59	34	7	4	9	8200	60	35	4	4	8	13.4	12.5	N	N	N	N	N	N
20.	DHIYA	5706	12/FC	8300	53	38	9	5	12	8900	60	40	5	4	10	11.9	12.0	N	N	N	N	N	N

LABORATORY INVESTIGATION REPORT OF THE PATIENTS

S.NO	NAME	OP. NO	AGE/ SEX	HEMATOLOGICAL ANALYSIS												Hb (gms%)		URINE ANALYSIS					
				BEFORE TREAATMENT						AFTER TREATMENT													
				TC	DC			ESR mm		TC	DC			ESR		BT	AT	BT			AT		
					P%	L%	E%	½ hr	1 hr		P%	L%	E%	½ hr	1 hr			Alb	Sug	Dep	Alb	Sug	dep
21.	ARVINI	3197	07/FC	8100	68	25	7	6	15	8900	65	32	3	04	08	12.1	11.5	N	N	N	N	N	N
22.	GATHSOPH	0775	09/MC	8900	45	47	8	22	42	8800	40	57	3	05	10	08.0	10.2	N	N	N	N	N	N
23.	LABISHA	8013	06/FC	9900	37	53	10	05	15	9200	45	52	3	04	10	13.1	12.5	N	N	N	N	N	N
24.	MUHAMMED KHAN	7750	$6^{1/2}$/MC	10100	45	49	6	06	15	8900	49	45	4	08	12	12.2	12.0	N	N	N	N	N	N
25.	SAI DHARSHINI	5847	10/FC	8100	70	24	6	03	12	8800	65	32	3	03	10	12.3	12.5	N	N	N	N	N	N
26.	DHARSHINI PRIYA	0711	08/FC	6400	46	47	7	08	15	7500	56	42	3	04	10	12.2	12.2	N	N	N	N	N	N
27.	ALKALF	8687	06/MC	10700	69	24	7	14	20	10900	65	30	5	05	10	14.3	13.2	N	N	N	N	N	N
28.	ILA MUKILAN	3025	06/MC	7100	43	45	9	05	15	8900	45	50	5	04	10	12.4	11.5	N	N	N	N	N	N
29.	YOGESH	8963	10/MC	12800	71	24	5	26	40	11600	62	34	4	05	10	13.4	12.5	N	N	N	N	N	N
30.	DHARNIKA	9338	06/FC	8800	62	33	5	03	05	8000	58	38	3	02	04	12.7	12.0	N	N	N	N	N	N
31.	SAMRITHA	4705	12/FC	8100	67	29	4	07	18	8900	65	32	2	05	10	11.3	11.2	N	N	N	N	N	N
32.	KAJAN KARTHICK	6994	06/MC	8900	36	56	8	22	42	9200	46	48	4	05	12	11.8	11.5	N	N	N	N	N	N
33.	SRI NISHA	6999	07/FC	8200	40	55	5	12	25	8500	50	40	8	10	20	11.6	11.2	N	N	N	N	N	N
34.	SUDHA	1896	08/FC	6800	46	48	6	21	39	7200	50	48	2	08	12	16.0	15.0	N	N	N	N	N	N
35.	AKSHAYA	9337	10/FC	9100	51	41	8	05	12	9800	57	40	2	03	10	11.2	12.0	N	N	N	N	N	N
36.	AYEESH	8014	08/MC	7200	54	41	5	10	18	7200	54	41	5	10	15	12.5	11.9	N	N	N	N	N	N
37.	VIGNESH WARAN	8045	$8^{1/2}$/MC	5300	72	22	6	03	08	6900	62	32	3	03	06	09.0	10.2	N	N	N	N	N	N
38.	MATHAN KUMAR	2040	11/MC	11100	58	34	8	15	35	10800	50	46	3	05	10	11.2	10.8	N	N	N	N	N	N
39.	PRASANTH	7301	06/MC	9900	54	39	7	07	18	8900	50	42	4	05	12	11.8	10.8	N	N	N	N	N	N
40.	DHIVYA LAKSHMI	5749	11/FC	8300	58	37	5	12	25	9800	60	38	2	06	12	12.0	12.5	N	N	N	N	N	N

EASI SCORE

ECZEMA AREA AND SEVERITY INDEX (EASI):

R - Redness T - Thickness
S - Scratching L - Lichenification

$EASI=0.1(E_H+T_H+S_{H+LH})A_H+0.2(E_U+T_U+S_{U+LU})A_U+0.3(E_T+T_T+S_{T+LT})A_T+0.4(E_L+T_L+S_{L+LL})A_L$

Redness/ Thickness/Scratching/Lichenification scoring:

0 - Nil
1- Mild
2- Moderate
3-Severe

AreaScoring:

0-Nil
1-1-9%
2- 10-29%
3-30-49%
4-50-69%
5-70-89%
6-90-100%

Easi score:
0 -clear
0.1 to 5.9 -mild
6.0 to 22.9 -moderate
23.0 to 72 -severe

S.NO	OP.NO	DETAILS		SYMPTOMS SCORE	
		NAME	AGE/SEX	BEFORE	AFTER
1)	5749	DHIVYA LAKSHMI	11/Fc	09.8	0.1
2)	9337	AKSHAYA	10/Fc	15.2	2.0
3)	8014	AYEESH	08/Mc	22.0	1.6
4)	6197	SAI GANESH	06/Mc	12.0	0.1
5)	5192	YOGESHWARAN	09/Mc	24.0	2.0
6)	1474	PREETHA	08/Fc	04.2	0.0
7)	5846	DHANUSHKA	08/Fc	16.2	0.1
8)	5106	DHIVYA	12/Fc	09.8	0.0
9)	9421	NITHYA	09/Fc	19.8	0.1
10)	4740	YUGASHNI	10/Fc	16.2	0.1
11)	6135	PRATHIKSHA	12/Fc	18.8	6.2
12)	3214	DHARSHINI	08/Fc	22.4	6.0
13)	8918	SAHITHA	$6^{1/2}$/Fc	15.2	4.8
14)	7000	MANJU	08/Fc	16.2	5.2
15)	6999	SRI NISHA	07/Fc	10.8	6.2
16)	0775	GATHSOPH	09/Mc	12.0	0.0
17)	9062	DHINAKARAN	08/Mc	07.2	0.0
18)	9338	DHARNIKA	06/Fc	15.2	0.0
19)	7301	PRASANTH	06/Mc	16.0	0.0

20)	9420	NANDHINI	09/Fc	09.8	0.0
21)	8013	LABISHA	06/Fc	12.0	0.0
22)	3197	ASHWINI	07/Fc	16.2	0.0
23)	4868	MANIKANDAN	11/Mc	09.8	0.0
24)	8687	ALKAIF	06/Mc	07.2	2.0
25)	5985	GANESH	08/Mc	15.2	0.0
26)	3198	MAHATH	08/Mc	21.6	0.0
27)	5847	SAI DHARSHINI	10/Fc	18.0	0.0
28)	5984	KAVIYA	07/Fc	22.4	0.0
29)	7750	MUHAMMED KHAN	$6^{1/2}$/Mc	16.4	0.0
30)	4705	SAMRITHA	12/Fc	09.6	0.0
31)	3025	ILA MUKILAN	06/Mc	12.0	0.0
32)	8674	DHINESH	12/Mc	26.0	0.0
33)	0711	DHARSHINI PRIYA	08/Fc	09.8	0.0
34)	8045	VIGNESHWARAN	$8^{1/2}$/Mc	16.2	2.0
35)	6994	KAJAN KARTHIK	06/Mc	07.2	0.0
36)	8963	YOGESH	10/Mc	09.6	0.0
37)	0787	NITHYA	07/Fc	04.0	0.0
38)	2040	MATHAN KUMAR	11/Fc	04.0	0.0
39)	1678	KAVIYA SRI	08/Fc	18.0	0.0
40)	1896	SUDHA	08/Fc	06.6	0.0

MC – MALE CHILD
FC – FEMALE CHILD

DISCUSSION

Bala karappan is a common skin disease in paediatric age group. This disease mostly resembles Atopic dermatitis in modern system. It is a chronic relapsing pruritic inflammatory skin disease in children associated with personal or family history of other atopic dermatitis like asthma, allergic rhinitis. Symptoms of atopic dermatitis are dryness, erythema, excoriation, exudation, fissuring, hyperkeratosis, lichenification, papulation, scaling and vesiculation .In this study 40 cases are treated in OPD of postgraduate department of Kuzhanthai Maruthuvam in Govt. Siddha Medical College, attached to Arignar Anna Hospital of Indian Medicine, Chennai-106 from 2016 -2019.

The patients were examined on siddha system of diagnosis with the help of modern investigations. The patients are treated with the trial drug *Saaranai ennai* (Internal & External) for 21 days.

The observations are described here.

1. Sex Distribution:

Among the 40 cases 23 patients were female children and 17 patients were male children. Mostly female children were affected.

2. Age Distribution:

Among the 40 cases, maximum numbers of patients 72.5% were in the age group of 6 to 9 years, 27.5% were in the age group of 9 to 12 years

3. Socio Economic status

Among the 40 cases, maximum numbers of patients 60% were in poor status, 35% were in middle class and 5% were in high class .The highest incidence was observed in poor class children due to poor hygienic, mal nutrition , exposure to polluted environment lower their immune response , so the poor children are more prone to the disease.

4. Family History

Among the 40 cases, 60% of the patients showed negative family history, 40% patients showed positive family history.

5. Dietary Habits

Among the 40 cases, 90% of the cases were mixed diet, 10% of cases were vegetarians.

6. According to Paruvakalam

Among the 40 cases, 25% cases were observed in *Munpanikalam*, 32.5% of cases in *Koothirkalam*, 10% cases in *kaarkalam* and *elavenil kalam* and 22.5% of cases observed in *pinpanikalam*. This study shows dryness of the skin due to cold climate may cause the skin diseases in this season .

7. Distribution of Thinai

Out of 40 cases, highest incidence 100% of cases were from in *Neithal* thinai.This is due to the fact that the study was conducted at Chennai a *Neithal land* and so majority of the cases were from that land. As per siddha literature *kabam* is affected in *neithal nilam* so it may aggravate the skin diseases.

8. Uyir Thathukkal

Vatham

Among the 40 cases, *Vyanan and Samanan* was affected in 100% patients, *Udhanan* was affected in 30% of patients, *Devadhathan* was affected in 25% of patients, *Abanan* was affected in 12.5% of patients and *Kirukaran* was affected in 12.5% of patients, *Pranan* was affected in 12.5% of patients. .

Pitham

Among the 40 cases,*Prasaga pitham* was affected in 40 patients. *Anarpitham* was affected in 12.5% of the patients and *ranjaga pitham* was affected in 82.5% of the patients. *Prasaga pitham* is responsible for complexion of the skin so it was affected in all cases(100%) .

Kabam

Out of 40 cases, *Kilethagam and Avalambagam* was affected 12.5% of the patients.

9. Udal thathukkal

Out of 40 patients *Saaram* was affected in all the cases, *Seneer* was affected in 33 (82.5%) cases and *Oon* was affected in 10 (25%)cases.

10. Ennvagai Thervugal

Out of 40 patients, *Niram and Sparisam* were affected in all the cases, *Naa* were affected in 82.5% of cases and *Malam* were affected in 12.5% of the patients .In this study 65% of patients have *Vatha Pitha Naadi* and 35% patients have *Pitha Vatha Naadi.*

11. Neikuri

Among the 40 cases, 25% of patients were having *Vatha neer*, 25% of patients were having *Pitha neer* and 50% of patients were having *Kaba neer.*

12. Clinical Features

Among the 40 patients. 100% of cases have itching, papules, and hyperpigmentation 95% of cases have erythema, 52.5% have scaling, Oozing and Lichenification have 47.5%, 50% have vesicles 12.5% have ulcer. After treatment 5% of cases have Ulcer, 10% of cases have Itching, 0ozing and Papules,12.5% cases have Scaling and Vesicles, 15% cases have Erythema and 22.5% of cases have lichenification.

13. Lab investigation

Routine examination of blood and urine were done before and after treatment. In most of the cases (85%) were having elevated ESR and increased eosinophil count and it has decreased after treatment.

14.Biochemical analysis

Qualitative analysis of the *Saaranai ennai* in the presence of iron which is more soluble and readily absorbable from that helps treating children who have associated anaemia. The study also indicates the presence of chloride.

15. Toxicity study of the drug:

The Acute and Sub-acute toxicity of the trial drug was carried out in Wistar albino rats reveals that the drug has no adverse effects, so it is safe to human beings.

16. Physicochemical analysis:

Saaranai ennai:

Viscosity at 50^{o}C (Pa s)	:	77.17
Refractive index	:	1.32
Weight per ml (gm/ml)	:	0.087
Iodoine value (mg I2/g)	:	95.25
Saponification Value (mg of KOH to saponify 1gm of fat)	:	174.8
Acid value mg KOH/g	:	1.047
Peroxidase value mEq/kg	:	4.987

17. Pharmacological analysis:

Pharmacological analysis showed the internal drug has significant Anti-histamine activity.

18. Statistical Analysis

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of **Bala Karappan (Atopic Dermatitis).** Hence it is concluded that the treatment was **effective and significant.**

19. **Result**

Among the 40 patient's good improvement is observed in 25 cases (62.5%), moderate improvement in 10 cases (25%) and mild improvement in 5cases (12.5%) and no adverse events observed clinically during the course of treatment.

SUMMARY

The clinical study was conducted with the trail drug *saaranai ennai* as Internal & external medicine for the disease *Bala karappan* in children. 40 patients were selected based on protocol. The study is conducted after being screened by the screening committee and approved by the Institutional Ethics committee(IEC) of Govt siddha medical college, chennai. Animal studies are carried, Hence, the study is safely executed on human volunteer patients and there was no adverse drug reactions noted during the study period.

40 children with Bala karappan diagnosed clinically treated in out patient department of Arignar Anna Hospital of Indian Medicine, Chennai-106. They were under gone laboratory investigation treated with trial drug, observed for clinical improvement and any adverse reaction of the drug .

I like to summarize this clinical study by the following:

- The efficacies of the trial drug saaranai ennai were studied and observed in this study.
- Clinical diagnosis of Bala karappan was done on the basisof clinical features described in Kuzhanthai maruthuvam (Bala vagadam) and Noi muthal nadal thirattu.
- The cost of the trial medicines are low, comparatively economic. These drugs are easily available and the dosage is also convenient.
- The potency of the trial drug reveals that the presence of chloride, Iron, flavonoids, glycosides, steroids, carbohydrates, triterepnoids, coumarins, phenols, saponins.
- The physico chemical analysis of the trial drug shows the safe and effectiveness of the drug with the following:

Viscosity at 50^{o}C (Pa s)	:	77.17
Refractive index	:	1.32
Weight per ml (gm/ml)	:	0.087
Iodoine value (mg I2/g)	:	95.25
Saponification Value (mg of KOH to saponify 1gm of fat)	:	174.8
Acid value mg KOH/g	:	1.047
Peroxidase value mEq/kg	:	4.987

- The pharmacological analysis of the drug reveals that it possesses very good acute and chronic anti histamine and immuno modulatory activity.
- Among the 40 cases treated 62.5% cases had shown Good improvement, 25% cases had shown Moderate improvement, 12.5% had shown Mild improvement.
- Observation made during the clinical study showed that the trial drug was clinically effective and has no adverse reaction among children.

CONCLUSION

Bala karappan is a common skin disorder in children and mainly caused by derangement of *kabha kuttram* followed by *vatham and pitham*. In this clinical study *"Saaranai ennai"* was taken as internal & External drug respectively. The deranged kuttram is settled down by the *kaippu suvai and inipu suvai* present in the trial medicine Saaranai ennai (Internal & External medicine) there by the medicine acts as *Ethirurai maruthuvam* to cure the disease.

Toxicological studies shows no acute and sub acute toxicity of the drug. The drug has Anti-Histamine activity.

The cost of the trial medicines are low.

During the clinical study no adverse events were observed.

The clinical study confirms the efficacy of the trial drugs by reducing the clinical signs and symptoms like itching, Papules, Oozing and scaling. . Clinical study results found to be Good in 62.5% cases, Moderate in 25% cases, and Mild in 12.5% cases. The Clinical trial conducted in selected patients was satisfactory and encouraging. The trial medicine is effective for *Bala karappan* in children. Through this study, the effectiveness of trial drug is confirmed and re-established by the author.

BIO STATISTICAL ANALYSIS

The most popular non parametric statistical tool, namely McNemat test analysis has been employed to analyse the effectiveness with the help of a hypothesis.

S.NO	Clinical features	Before Treatment		After Treatment	
		No.of cases	Percentage	No.of cases	Percentage
1	Itching	40	100%	4	10%
2	Vesicles	20	50%	5	12.5%
3	Oozing	19	47.5%	4	10%
4.	Papules	40	100%	4	10%
5	Scaling	21	52.5%	5	12.5%
6	Erythema	38	95%	6	15%
7	Hyperpigmentation	40	100%	10	25%
8	Ulcer	5	12.5%	2	5%
9	Lichenification	19	47.5%	9	22.5%

Mc nemat test, C.I: 95%, $^{*}P<0.05$; **,0.01

Software: spss 20 version

Number of cases: 40

Inference:

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of **BALA KARAPPAN (Atopic dermatitis)**. Hence it is concluded that the treatment was effective and significant.

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LOYOLA COLLEGE

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College of Excellence, NAAC Acredited A++, Chennai - 600 034. Tamil Nadu.

National Conference on

Biochemistry and Therapeutics of Diabetes and Cancer Treatment & Challenges

(BTDCTC - 2019)

February 28 & March 1, 2019

Organised by

Ethnopharmacology and Microbial Biotechnology Lab,
Department of Plant Biology and Biotechnology

Certificate

This is to certify that ~~Mr./Ms.~~/Dr. T. Suvathini of Govt. Siddha Medical College, Chennai has participated / ~~presented~~ a paper (Oral/Poster) in the National Conference on Biochemistry and Therapeutics of Diabetes and Cancer Treatment & Challenges (BTDCTC-2019) held on February 28 & March 1, 2019.

D. Agastian
Dr. P. AGASTIAN
CONVENOR, BTDCTC-2019
Dept. of Plant Biology & Biotechnology

Rev. Dr. F. ANDREW, S.J
PRINCIPAL
Loyola College

International Conference on

"Sports Medicine, Yoga, Fitness Therapy & Rehabilitation"

SYFTR-2019

Date: 11th and 12th March 2019

CERTIFICATE

This is to certify that Mr/Ms/Dr/Prof T. SWATHINI, GOVT. SIDDHA MEDICAL COLLEGE has participated/Chaired a session in the International conference, organized by Research and Development wing, Sree Balaji Medical College & Hospital, Chromepet, Chennai, Tamil Nadu, India. He/she has presented a Paper entitled on_____ and the CME Points Awarded_____

Prof . S. Benjamin Prakash
German University of Physical Education & Sports Sciences Cologne,Germany

Prof. Senthamil R. Selvan
Principal Scientist, Biomarker Strategies Rockville, MD,USA

Prof.W.M.S. Johnson
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Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai.
Approved by Pharmacy Council of India, New Delhi, and
All India Council for Technical Education, New Delhi

CERTIFICATE

This is to certify that the project title "AN OPEN CLINICAL STUDY ON BALA KARAPPAN (ATOPIC DERMATITIS) in children with the evaluation of siddha trial drug SAARANAI ENNAI for its toxicological and ANTI HISTAMINE activity in Wistar albino rats" has been approved by IAEC

IAEC No: LV/13/CLBMCP/2018

C.L. Baid Metha College of Pharmacy ★ CHENNAI-97 ★ Thoraipakkam

Dr.P.Muralidharan

Government Siddha Medical College
Department of Medicinal Botany

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,
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AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given to Dr. T. Swathini B.S.M.S. doing M.D. (S) in Department of Kuzhanthai maruthuvam at Government Siddha Medical College, Arumbakkam, Chennai-106 is identified below as

S.NO	DRUG NAME	BOTANICAL NAME	FAMILY NAME
1	SAARANAI VER	*TRIANTHEMA DECANDRA*	AIZOACEAE
2	UTHAMANI VER	*PERGULARIA DAEMIA*	ASCLEPIADACEAE
3	MUDAKOTHAN VER	*CARDIOSPERMUM HALICACABRUM*	SAPINDACEAE
4	SIRIA VAZHUTHALAI VER	*SOLANUM MELONGENA*	SOLANACEAE
5	YERUKKU VER	*CALOTROPHIS GIGANTIA*	APOCYNACEAE
6	MURUNGAI VER	*MORINGA OLEIFERA*	MORINGACEAE
7	PUNGAN VER	*PONGAMIA PINNATA*	FABACEAE
8	KAZHARCHI	*CAESALPINIA BONDUC*	FABACEAE
9	MILAGU	*PIPER NIGRUM*	PIPERACEAE
10	ULLI	*ALLIUM SATIVUM*	AMARYLLIDACEAE
11	BOODHA KARAPPAN PATTAI	*STERCULIA FOETIDA*	MALVACEAE
12	VASAMBU	*ACORUS CALAMUS*	ACORACEAE
13	AMANAKKU ENNAI	*RICINUS COMMUNIS*	EUPHORBIACEAE

References: Flora of Presidency, Gamble, J. S

Date: 05.04.2018

Place: Chennai

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INSTITUTIONAL ETHICS COMMITTEE

Date : 06.04.2017
Sub : IEC Review of research proposals
Ref : Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
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Dr. K. KANAKAVALLI., MD(S)., Member secretary	✓	6.4.17
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Dr.R.VASUDEVAN, M.D(S)., PG.DIP (Clinical research), Msc (Medical sociology), Sociologist	✓	6/4/17
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Mrs. PREETHA SARAVANAN, Public person		

Dr.P.Jeya prakash narayanan M.D(s).,
Chairman

6.4.17
Dr.K.Kanakavalli, M.D(s)
Member secretary

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-2/020/2017

Protocol title: AN OPEN CLINICAL STUDY ON BALA KARAPPAN (ATOPIC DERMATITIS) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG SAARANAI ENNAI (INT & EXT)
Principal Investigator: Dr.T.SWATHINI
Name & Address of Institution: Government Siddha Medical College, Arumbakkam, Chennai-106
☑ New Review ☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY): 06-04-2017 Date of Previous Review, If RevisedApplication:
Decision of the IEC ☐ Recommended ☑ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions / Reasons / Remarks:1.Change dosage 1-2ml.2.Change age 6-12 years.3.change manal patham in external,mezhugu patham in internal.
Recommended for a period of 1 year from date of completion of preclinical studies :

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.K.Kanakavalli 6.4.17
Member Secretary

The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/~~Mr~~/~~Mrs~~.....T. SWATHINI.....

For participating as ~~Resource Person~~ / Delegate in the Twenty Fourth Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

For ***AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 24th to 28th April 2017.

Dr.N.KABILAN, M.D.(S).Ph.D.,
PROF & HEAD DEPT.OF SIDDHA

Prof.**Dr.T.BALASUBRAMANIAN,** M.D.,D.L.O.,
REGISTRAR

Prof.**Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"SAARANAI ENNAI (INT & EXT)"** IN THE TREATMENT OF

"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN

FORM l - SCREENING AND SELECTION PROFORMA

1. **OP NO : ……**
2. **NAME : ……**
3. **AGE : ……**
4. **GENDER : ……**
5. **F.OCCUPATION : ……**
6. **F.INCOME : ……**
7. **ADDRESS : ……**

   ……

   ……
8. **CONTACT NO : ……**

INCLUSION CRITERIA:

- Age : 6-12 Yrs Yes / No
- Itching Yes / No
- Patient having symptoms of erythema,vesicles, oozing. Yes/No
- Patient having symptoms of lichenification Yes/No
- Patients who are willing to undergo Laboratory investigation. Yes / No
- Patients who are willing to sign the informed consent stating that he/ she will conscientiously stick to the treatment during 48days but can opt out of the trial of his/ her own conscious discretion. Yes / No

EXCLUSION CRITERIA

(Clinical history)

- History of scabies
- History of photo dermatitis
- History of secondary bacterial infection
- History of furunculosis

ADMITTED TO TRIAL:

YES **NO**

If yes, **OPD/IPD**

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE
CHENNAI-600 106

CLINICAL STUDY ON **"SAARANAI ENNAI (INT & EXT)"** IN THE TREATMENT OF**"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN**

FORM lI -HISTORY TAKING PROFORMA

1. **SERIAL NO OF THE CASE :**
2. **OP/IP NO :**
3. **NAME :**
4. **AGE :**
5. **GENDER :**
6. **F. OCCUPATION :**
7. **INCOME :**
8. **COMPLAINTS & DURATION:**
9. **PERSONAL HISTORY :**
10. **HISTORY OF PREVIOUS ILLNESS**
11. **BIRTH HISTORY**

12. DIETARY HABIT :

- Vegetarian
- Non-vegetarian

13. FAMILY HISTORY :

Whether this problem runs in family?

1. Yes 2.No

If yes, mention the relationship of affected person(s) ----------

History of previous investigations if any ----------

Date:

Station

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

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CHENNAI – 600 106

CLINICAL STUDY ON **"SAARANAI ENNAI (INT & EXT)"** IN THE TREATMENT OF

"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN

FORM III- CLINICAL ASSESSMENT PROFORMA

1. **SERIAL NO : …….**
2. **OP / IP NO : …….**
3. **NAME : …….**
4. **AGE : …….**
5. **GENDER : …….**

GENERAL EXAMINATION:

Height (cms) : …….

Weight (kg) : …….

Temperature(°F) : …….

Pulse rate(/min) : …….

Heart rate(/min) : …….

Respiratory rate(/min) : …….

Blood pressure(mm/Hg) : …….

	Present	**Absent**
Pallor		
Jaundice		
Cyanosis		
Lymphadenopathy		
Pedal edema		

Clubbing

Jugular vein pulsation

SYSTEMIC EXAMINATION

CardioVascular System : …….

Respiratory system : …….

Gastro-intestinal system : …….

Central Nervous System : …….

Urogenital system : …….

Endocrine System : …….

SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

1. Vathaudal
2. Pithaudal
3. Kabaudal
4. Thon

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

1. Kurinji (Hilly terrain)
2. Mullai (Forest range)
3. Marutham (Plains)

4. Neithal (Coastal belt)

5. Paalai (Arid regions)

3. KAALAM:

1. Kaarkaalam 4.Pinpani kaalam
2. Koothirkaalam 5. Ilavenilkaalam
3. Munpanikaalam 6.Muthuvenil kaalam

4. GUNAM:

1.Sathuvam 2.Raasatham 3.Thaamatham

5. IMPORIGAL (SENSORY ORGANS):

Normal/Affected

Mei _____

Vaai _____

Kann _____

Mukku _____

Sevi _____

6. KANMENDHIRIYAM (MOTOR ORGANS):

Kai _____

Kal _____

Vaai _____

Eruvai_____

Karuvaai _____

7. KOSANGAL (SHEATH):

Annamayakosam _____

Pranamayakosam _____

Manomayakosam _____

Vignanamayakosam_____

Anandamayakosam _____

8. UYIR THAATHUKKAL: [THREE HUMORS] (VALI, AZHAL, IYAM)

A) VALI

Pranan _____

Abanan _____

Samanan _____

Uthanan _____

Vyanan _____

Naagan _____

Koorman _____

Kirukaran _____

Devathathan _____

Dhananjayan _____

B) AZHAL

Analakam _____

Ranjakam _____

Sathakam _____

Prasakam _____

Alosakam _____

C) IYAM

Avalambagam _____

Kilethagam _____

Pothagam _____

Tharpagam _____

Santhigam _____

9. SEVEN UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

Saram _____

Senneer _____

Oon _____

Koluppu _____

Enbu _____

Moolai_____

Sronitham _____

10. ENVAGAI THERVU:

I. NAADI : [PULSE PERCEPTION]

II. SPARISAM : [PALPATION]

III. NAA : [TONGUE]

IV.NIRAM : [COMPLEXION]

1. Vadham
2. Pitham
3. Kabam

V.MOZHI: [VOICE]

1. High Pitched
2. Low Pitched
3. Medium Pitched

VI.VIZHI : [EYES]

VII. MALAM: [BOWEL HABITS / STOOLS]

Niram

Irugal

Ilagal

Others

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Niram

Manam

Edai

Nurai

Enjal

NEIKKURI

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

CLINICAL STUDY ON **"SAARANAI ENNAI (INT & EXT)"** IN THE TREATMENT OF

"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN

FORM IV : LABORATORY INVESTIGATIONS PROFORMA

1. **SERIAL NO OF THE CASE : _____**
2. **OP / IP NO : _____**
3. **NAME : _____**
4. **AGE : _____**
5. **GENDER : _____**

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		**BEFORE TREATMENT**	**AFTER TREATMENT**
Hb (gm/dL)			
Absolute eosinophil count (Cells/ul)			
ESR (mm)	**½ hr.**		
	1 hr.		
T.WBC (Cells / Cu.mm)			
Differential Count (%)	**Polymorphs**		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

B) URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Deposits		

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"SAARANAI ENNAI (INT &EXT)"** IN THE TREATMENT OF**"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN**

FORM V: INFORMED CONSENT FORM

*"**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it to my satisfaction.***

***I consent voluntarily to participate my chid in this study and understand that I have the right to withdraw my child from the study at any time without in any way it affecting my chid further medical care**".*

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

*"**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely**."*

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Guide: **Signature of the Investigator:**

அரசுசித்தமருத்துவக் கல்லூரி, சென்னை-106

அறிஞர் அண்ணாமருத்துவமனை,சென்னை

பாலகரப்பான் நோய்க்கானசித்தமருந்தின் **(சாரணைஎண்ணெய்)**

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவஆய்விற்கானதகவல் படிவம்
ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது.
நான் இந்தஆய்வைகுறித்தஅனைத்துவிபரங்களையும் நோயாளிக்குபுரியும் வகையில் எடுத்துரைத்தேன் எனஉறுதியளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்தமருத்துவஆய்வின் காரணத்தையும்,மருந்தின் தன்மைமற்றும் மருத்துவவழிமுறைபற்றியும்,தொடர்ந்துஎனதுஉடல்
இயக்கத்தைகண்காணிக்கவும்,அதனைபாதுகாக்கவும் பயன்படும் மருத்துவஆய்வுக்கூட பரிசோதனைகள் பற்றிதிருப்திஅளிக்கும் வகையில் ஆய்வுமருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் எனதுகுழ்ந்தையின் இந்தமருத்துவஆய்வின் போதுகாரணம் எதுவும் கூறாமல்,எப்பொழுதுவேண்டுமானாலும்
இந்தஆய்விலிருந்துஎனதுகுழந்தையைவிடுவித்துகொள்ளும்
உரிமையைதெரிந்திருக்கின்றேன். நான் என்னுடையசுதந்திரமாகதேர்வுசெய்யும் உரிமையைக் கொண்டுநோய்க்கானசிற்றாமுட்டிநெய் மருந்தின் பரிகரிப்பும் திறனைக் கண்டறியும் மருத்துவஆய்விற்குஎன்னைஉட்படுத்தஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

தேதி: சாட்சிக்காரர் கையொப்பம்:

இடம்: பெயர்:

உறவு:

துறைத்தலைவர் கையொப்பம்: ஆராய்ச்சியாளர் கையொப்பம்:

GOVERNMENT SIDDHA MEDICAL COLLEGE, CHENNAI

CLINICAL STUDY ON **"SAARANAI ENNAI"** IN THE TREATMENT OF **"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN**

FORM VI - WITHDRAWAL FORM

SI NO :

OP / IP NO :

NAME :

AGE / GENDER :

DATE OF TRIAL COMMENCEMENT :

DATE OF WITHDRAWAL FROM TRIAL :

REASONS FOR WITHDRAWAL:

- Long absence at reporting Yes/ No
- Irregular treatment Yes/ No
- Shift of locality Yes/No
- Increase in severity of symptoms Yes/No
- Development of severe adverse drug reactions Yes/No

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"SAARANAI ENNAI"** IN THE TREATMENT OF

"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN

FORM VII – PATIENT INFORMATION SHEET

Name of Co- Investigator:T.Swathini

Name of the college: Govt.SiddhaMedical College, Arumbakkam, Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I,T.SWATHINI studying M.D (Siddha) at Govt.Siddha Medical College, Chennai, is doing a clinical trial on ''Balakarappan" – **(**Atopic dermatitis)in children . It is becoming a most common disease, occurring throughout the world. In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine "saaranaiennai"(Internal & External medicine) 1-2 ml(INT) and 30 ml(EXT) for 21 days.

The information I am collecting in this study will remain between you and the Co-investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact T.Swathini, PG Scholar cum Co- investigator of this study, attached to Govt. Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Govt.Siddha Medical College, Chennai.

அரசுசித்தமருத்துவக் கல்லூரி, சென்னை-106

அறிஞர் அண்ணாமருத்துவமனை,சென்னை

பாலகரப்பான் நோய்க்கானசித்தமருந்தின் **(சாரணைஎண்ணெய்)**

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவஆய்விற்கானதகவல் படிவம்

ஆராய்ச்சியாளர் பெயர்: மருத்துவர்.தி.சுவாதினி

நிறுவனத்தின் பெயர்:அரசுசித்தமருத்துவக் கல்லூரி,அரும்பாக்கம்,சென்னை-106

அரசுசித்தமருத்துவக் கல்லூரியில் பட்டமேற்படிப்புபயின்றுவரும் நான் மருத்துவர்

தி.சுவாதினி**பாலகரப்பான்** என்னும் நோயில் மருத்துவஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இந்த நோய் பரம்பரையாகவும் ஒவ்வாதஉணவுப்பொருட்களைஉட்கொள்வதாலும் ஒவ்வாமையைஏற்படுத்தும் பொருட்களின் மேல் அடிக்கடிஉராய்வதினாலும் உண்டாகிறது. இதுபரவக் கூடியநோயல்ல.

இந்தஆராய்ச்சிசம்பந்தமாகசிலகேள்விகளைக் கேட்கவும்,தேவையானஆய்வகப் பரிசோதனைக்குதங்கள் குழந்தையைஉட்படுத்தவுமஉள்ளேன்.

இந்தஆராய்ச்சிக்குதங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்நாகசாரணைஎண்ணெய் 1-2மிலிமற்றும் வெளிமருந்தாக 30மில்லி பயன்படுகின்றது.

இந்தமருந்துசிறப்பாகபாண்டுநோய்க்காகஅங்கீகரிக்கப்பட்டசித்தமருத்துவ நூலில் கூறப்பட்டுள்ளது

இந்தஆராய்ச்சியில் தங்களைஅனுமதித்தபிறகுஉங்களுக்குவிருப்பம் இல்லையெனில் எப்போதுவேண்டுமானாலும் ஆராய்ச்சியில் இருந்துவிலகிக் கொள்ளஉரிமைஉள்ளது.

இந்தஆராய்ச்சிக்குசம்பந்தமாகநோயின் தன்மைபற்றியும் மற்றவிபரங்களுக்கும் **ஆராய்ச்சியாளர் மருத்துவர்:** தி.சுவாதினி (பட்டமேற்படிப்பாளர்,குழந்தைமருத்துவத் துறை) அவர்களைஎந்தநேரத்திலும் தொடர்புகொள்ளலாம். கைப்பேசிஎண்:9087674097. மேலும் இந்தஆராய்ச்சிக்குதக்கஅனுமதிச் சான்று (IEC) பெறப்பட்டுள்ளது.

இந்த்றிலும் பாதுகாப்பான மூலிகைபொருட்களைக் கொண்டுதயாரிக்கப்பட்டுள்ளது. பக்கவிளைவுகளைஏற்படுத்தாது. மேலும் உணவுமுறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறுஅறிவுறுத்தபடுகிறது.

இது சம்பதமானதங்களதுஅனைத்துவிவரங்களும் ரகசியமாகவைக்கப்படும் எனஉறுதிஅளிக்கிறேன்.

இதில் பயணப்படிமுதலியஎந்தஉதவித் தொகையும் வழங்கப்படமாட்டாது. இந்தஆராய்ச்சியின் போதுஉடலுக்குவேறுபாதிப்புஏற்படும் பட்சத்தில் அறிஞர் அண்ணாமருத்துவமனையில் தக்கசிகிச்சைஅளிக்கப்படும்.

அரசினர் சித்த மருத்துவக் கல்லூரி

அறிஞர் அண்ணா இந்திய மருத்துவமனை சென்னை- 10 6

கரப்பான் நோயாளிகள் கடைப்பிடிக்க வேண்டிய உணவு வழிமுறைகள்

உணவில் சேர்க்க வேண்டியவை :

- பச்சைகாய்கறிகள்
- கீரைவகைகள்
- திரிதோடசமபொருட்கள் (ஏலம், மஞ்சள், சீரகம், பெருங்காயம், மிளகு, சுக்கு, வெந்தயம், பூண்டு)
- முளைகட்டியதானியங்கள்
- பழவகைகள்
- தண்ணீர்

உணவில் தவிர்க்க வேண்டியவை

- கரப்பான்பண்டங்களானவரகு, கம்பு, சோளம், வாழைக்காய், பாகற்காய்
- மீன்வகைகள், முட்டை, கருவாடு, கோழிக்கறி
- கத்தரிக்காய்
- புளி
- ஊறுகாய்வகைகள்
- அதிகஅளவுஉப்பு

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"SAARANAI ENNAI"** IN THE TREATMENT OF

"BALA KARAPPAN'' (ATOPIC DERMATITIS) IN CHILDREN

FORM X - ADVERSE REACTION REPORTING FORM

SERIAL NO :

OP/IP NO :

NAME :

AGE :

GENDER :

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION:

TIME :

DESCRIPTION OF ADVERSE REACTION:

MANAGEMENT :

Date:

Station:

Signature of the Guide **Signature of the Investigator**

DEPARTMENT OF KUZHANTHAI MARUTHUVAM

DISSERTATION STUDY ON SAARANAI ENNAI IN BALA KARAPPAN (ATOPIC DERMATITIS) IN CHILDREN

INVESTIGATOR- DR.T.SWATHINI
ANNA HOSPITAL OPD-CHENNAI-106

OPNO/DATE:

Name :

Age/sex :

Parent name :

Address :

Pnone no :

COMPLAINTS AND DURATION:

Erythema,itching,papules,oozing,scaling,

Vesicles,pustules,oedema,ulcer/

Lichenification

SITES :

STAGE : ACUTE / SUBACUTE/ CHRONIC

MODE OF ONSET : ACUTE/ CHRONIC

ECONOMIC STATE: POOR / MIDDLE / RICH

DIET : VEG/MIXED

FAMILY HISTORY:

PAST HISTORY :

CONTACY ALLERGY/FOOD ALLRGY:

ON EXAMINATION:

PALLOR

HT

WT

CVS

RS

OTHERS

ENVAGAI THERVU:

Naa : Malam :

Niram : Moothiram :

Mozhi : Naadi :

Vizhi : Sparisam :

INVESTIGATION

	BEFORE TREATMENT	AFTER TREATMENT
Blood Tc Dc Hb Esr Urine Alb Sug Dep Motion Ova Cyst others		

TREATMENT

WEEKS/DATE	Erythema	itching	Vesicles, oozing	Scaling/ pustules	Oedema/ Ulcer	lichenification
I						
II						
III						
IV						
V						
VI						
VII						

RECURRENCE:

RESULTS:

EASI SCORE ASSESSMENT:

EASI SCORE	0 day	7^{th}	14^{th}	21^{st}

ECZEMA AREA AND SEVERITY INDEX (EASI):

R - Redness T - Thickness
S-Scratching L -Lichenification

$EASI=0.1(E_H+T_H+S_{H+LH})A_H+0.2(E_U+T_U+S_{U+LU})A_U+0.3(E_T+T_T+S_{T+LT})A_T+0.4(E_L+T_L+S_{L+LL})A_L$

Redness/ Thickness/Scratching/Lichenification scoring:

0 - Nil
1- Mild
2- Moderate
3-Severe

AreaScoring:

0-Nil
1-1-9%
2- 10-29%
3-30-49%
4-50-69%
5-70-89%
6-90-100%

EASI Calculation				
Patient name				
Date				
RATING SCORE	**0=Nil**	**1=Mild**	**2=Moderate**	**3=Severe**

SEVERITY SCORE	**Body region and Area score**			
	Head/Neck	**Upper Limbs**	**Tru**	**Lower Limbs**
Erythema				

Thicness					
Scratching					
Lichenification					
Weighting factor x		0.1	0.2	0.3	0.4
Involvement Total =					
Surface area					
Degree of involvement as % for each body region affected (score each region between 0 and 6)	**0 = None**				
	1 = 1-9%				
	2 = 10-29%				
	3 = 30-49%				
	4 = 50-69%				
	5 = 70-89%				
	6 = 90-100%				
Surface Area Total =					
Involvement Total x Surface Area Total =					
TOTAL SCORE =					

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVT SIDDHA MEDICAL COLLEGE AND HOSPITAL CHENNAI

Branch -IV KUZHANTHAI MARUTHUVAM

PROFORMA OF CASE SHEET FOR *BALA KARAPPAN*

OP. No	:	Nationality	:
Name	:	Religion	:
Age	:	Date of Admission	:
Sex	:	Date of Discharge	:
Address	:	Diagnosis	:
Informant	:	Medical Officer	:

1. Complaints and duration :

2. History of present illness :

3. History of Past illness :

4. Antenatal history :

5. Birth history :

6. Neonatal history :

7. Developmental history :

8. Nutritional history :

9. Immunization history :

10. Family history :

11. Socio economic status :

General examination

1. Appearance and posture :

2. Nutritional status :

3. Anaemia :

4. Cyanosis :

5. Clubbing :

6. Jaundice :

7. Lymphadenopathy :

8. Abdominal distension :

9. Pedal oedema :

Vital Signs

1. Temperature :

2. Pulse rate :

3. Respiratory rate :

4. Heart rate :

5. Blood pressure :

Anthropometry

a. Height :

b. Weight :

c .Chest circumference :

SIDDHA ASPECTS

Nilam

1. Kurinji :

2. Mullai :

3. Marutham :

4. Neithal :

5. Paalai :

Paruvakaalam

1. Kaar:

2. Koothir :

3. Munpani :

4. Pinpani :

5. Elavenil :

6. Muthuvenil :

Poripulangal

1. Mei :

2. Vai :

3. Kan :

4. Mooku :

5. Sevi :

Kanmenthiriyam

1. Kai :

2. Kaal :

3. Vaai :

4. Eruvai :

5. Karuvai :

Uyirthathukkal

Vadham

1. Praanan :

2. Abaanan :

3. Viyaanan :

4. Uthaanan :

5. Samaanan :

6. Naagan :

7. Koorman :

8. Kirukaran :

9. Devathathan :

10. Dhananjeyan :

Pitham

1. Analpitham :

2. Ranjagam :

3. Saadhagam :

4. Praasagam :

5. Aalosagam :

Kabam

1. Avalambagam :

2. Kiletham :

3. Pothagam :

4**.** Tharpagam :

5**.** Santhigam :

Udalkattugal

1. Saaram :

2. Senneer :

3. Oonn :

4. Kozhuppu :

5. Enbu :

6. Moolai :

7. Sukkilam / Suronitham:

Envagaithervugal

1. Naadi :

2. Sparisam :

3. Naa :

4. Niram :

5. Mozhi :

6. Vizhi :

7. Malam :

8. Moothiram :

MODERN ASPECTS

1. Respiratory System :

2. Cardiovascular system :

3. Gastro intestinal system :

4. Central nervous system :

5. Excretory system :

Signs and Symptoms of BalaKarappan

Itching :

Papules :

Erythema :

Vesicles :

Scaling :

Oozing :

Hyperpigmentation:

Laboratory investigations

Blood

TC :

DC :

ESR

1/2 hr:

1 hr :

Hb% :

Urine

Albumin :

Sugar :

Deposits :

Investigation -Siddha aspect

1. Neerkuri

Niram :

Edai :

Manam :

Nurai :

Enjal :

2. Neikuri

3. Trial Drugs:

Saaranaiennai(Internal& External)

6 to 12 yrs: 1-2 ml (int) and 30 ml (ext)

3.Daily progress

Date	**Symptoms**	**Medicine**

GOVT. SIDDHA MEDICAL COLLEGE AND HOSPITAL,

POST GRADUATE DEPARTMENT. CHENNAI.

Branch -IV KUZHANTHAI MARUTHUVAM

ADMISSION - DISCHARGE CASE SHEET

Name of the Medical Unit:

IP. NO :

Bed no :

Ward :

Name :

Age :

Sex :

Permanent address :

Temporary address :

Informant :

Occupation :

Income :

Nationality :

Religion :

Date of Admission:

Date of discharge:

Diagnosis :

Medicalofficer :

S.No	CLINICALFEATURES (Signs and Symptoms)	During Admission	During Discharge
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			